United States Court of Appeals

for the Second Circuit

APPENDIX

ORIGINAL WITH PROOF OF SERVICE

76-6169

UNITED STATES COURT OF APPEALS

for the

SECOND CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

-against-

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR,

Defendants-Appellants,

and

NATIONAL FISHERIES INSTITUTE,

Intervenor-Appellant.

On Appeal from a Judgment of the United States District Court for the Eastern District of New York

JOINT APPENDIX

(Volume I of II - Pages A-1 - A-404)

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DOCKET ENTRIES

DISTRICT CODE	DOCKET NUMBER	FILING DATE MO.	DAY	YEAR	J	N/S	DEMAND OTHER	JUDGE NUMBER	JURY DEM.	DOCKET YR.	DOCKET NUMBER
207/1	76	0647	04	07	76	1	520	0713		DOOLING	

PLAINTIFFS	DEFENDANTS
U.S.A. UNISED STATES OF AMERICA	NOVA SCOTIA FORD PRODUCTS CORP NOVA SCOTIA FOOD PRODUCTS CORP., a corporation, and DAVID SKLAR and EMANUEL SKLAR, individuals and NATIONAL FISHERIES INSTITUTE deft. interv.

CAUSE

28 USC 1345 - civil injunction under 21 USC 332 to enjoin violation of 21 USC 331, the Federal Food, Drug and Cosmetic Act.

ATTORNEYS

For PLNIFF:
DAVID G. TRAGER
UNITED STATES ATTORNEY -EDNY
By: DAVID W. McMORROW

FOR NATIONA FISHERIES INST.
Kleinfeld Kaplan & Becker
1200 17th St. N.W.
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UNITED STATES DISTRICT COURT DOCKET

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DOCKET ENTRIES

76C 647 USA vs NOVA SCOTIA PRODUCTS INC. et al

DATE	NR.	PROCEEDINGS
4-7-76		Complaint filed. Summons issued. (1) (c
4-8-76		Memorandum of points and authorities in support of preliminary injunction filed. (2)
4/9/76		Summons retd and filed. Executed. (3)
4/9/76		Before DOOLING,J.- Application for T.R.O. denied-Application for preliminary injunction -Consolidated with trialof the action-Trial date -May 3, 1976
4-09-76		Stenographer's transcript dtd 4-8-76 filed. (4)
4-14-76		Letter from Joseph H. Einstein dtd 4-13-76 filed. (5)
5-5-76		Before DOOLING,J.- Case called for conf and Judge rules on defts requests for documents
5-6-76		Amended answer of defts filed. (6)
5-6-76		Defts request for production of documents filed. (7)
5-12-76		Memo in support of motion to convene filed with motion of Nat'l Fisheries Institute's motion to intervene. Ret 5-17-76. (8/9)
5-12-76		ANSWER OF Nat'l Fisheries Institute filed. (10)
5-13-76		USA's reply to counterclaims of defts filed. (11)
5-14-76		Affidavit of Arnold Isaac Friede filed with administrative record. (12)
5-17-76		Supp. memo of USA in support of perliminary injunction filed, (13)
5-17-76		USA reply to counterclaim of National Fisheries filed. (14)
5-17-76		Defendants joint trial brief ifled. (15)
5-17-76		By DOOLING,J.-ORDER GRANTING INTERVENTION dtd 5-17-76 filed.Nat'l Fisheries Institute is permitted to intervene as a deft. p/c
5-17-76		Before DOOLING,J.-Case called. Motion for intervention argued & granted. Trial ordered & begun. Deft moves for dismissal of the complaint-decision reserved. Trial adj'd to 5-18-76. (16)
5/18/76		Before DOOLING,J.- Case called- Trial resumed-Adjd to 5/19/76
5/19/76		Before DOOLING,J.- Case called- Trial resumed-Deft rests-Govt rests-Post Trial Briefs due 6/21/76 -Reply Briefs due 7/2/76
5-20-76		Transcript dtd. 5-17-76/ 5-18-76 and 5-19-76 filed. (17/18/19)
6-22-76		Govt's post trial memorandum of points etc filed. (20)
7-1-76		Post trial reply brief of defts filed. (21)
7-2-76		Govt's post trial reply memorandum filed. (22)
7-8-76		Post trial ~~brief~~ rebuttal brief of defts &intervenor filed, (23)
8-17-76		By DOOLING,J-Memo incorporating findings of fact and Order dtd 8-17-76 directing the Government to draft a decree in accordance with this opinion etc. It is concluded that there is not necessity for any fruther hearing in this Court or for a remand to the Commissioner for reconsideration in the light of matters not before him or not adequately considered by him at the time the regulation was adopted. mg p/c
10-7-76		Govt's memo in support of proposed decree filed. (24)
10-14-76		Defts' supplemental affidavit of Joseph H. Einstein filed. mg (25)
10-14-76		Defts' memorandum in connection with proposed judgment and request for a stay pending appeal filed. (26)
10-18-76		By DOOLING,J-Order dtd 10-15-76 that defts' motion for a stay pending appeal is denied. (27)
10-18-76		By DOOLING,J-Final judgment dtd 10-15-76 enjoining defts from manufacturing and processing for distribution whitefish unless whitefish are manufactured and processed by them in conformity with the regualtions contained in 21CFR 128a, etc filed. p/c (28)
11-3-76		Notice of appeal filed. (defts) 29 30

DOCKET ENTRIES

CIVIL DOCKET CONTINUATION SHEET

PLAINTIFF	DEFENDANT	DOCKET NO. 76-C-54
USA	NOVA SCOTIAX PRODUCTS et al	PAGE ___ OF ___ PA

DATE	NR.	PROCEEDINGS
11-8-76		Civil appeal ~~xxx~~ & scheduleing order filed.
11-9-76		Affidavit of service filed.
11-15-76		Unsigned decree of permanent injunction of pltff filed.
11-15-76		Notice of settlement of defts proposed judgment etc., filed.

COMPLAINT

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

United States of America, Plaintiff v. NOVA SCOTIA FOOD PRODUCTS CORP., a corporation, and DAVID SKLAR and EMANUEL SKLAR, individuals, Defendants	COMPLAINT FOR INJUNCTION CIVIL ACTION NO._____

The UNITED STATES OF AMERICA appearing by its attorney David G. Trager, United States Attorney for the Eastern District of New York, respectfully represents unto this Honorable Court as follows:

1. This proceeding is brought under Section 302(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332(a)), which section specifically invests the several district courts of the United States with jurisdiction to enjoin and restrain violations of said Act.

2. The defendant, Nova Scotia Food Products Corp., is a corporation organized and existing under the laws of the State of New York and trading and doing business at 77 Lombardy Street, Brooklyn, New York, within the jurisdiction of this Court.

3. The defendant, David Sklar, an individual, is president of said corporation and performs his duties as such at 77 Lombardy Street, Brooklyn, New York, within the jurisdiction of this Court.

4. The defendant, Emanuel Sklar, an individual, is the vice president and treasurer of said corporation and performs his duties as such at 77 Lombardy Street, Brooklyn, New York, within the jurisdiction of this Court.

5. The defendants have been and are now engaged at their plant at 77 Lombardy Street, Brooklyn, New York, in

ufacturing, processing, packing, holding, and distributing -process smoked fish, foods within the meaning of 21 U.S.C. 3 (f), while held for sale after shipment in interstate commerce.

6. Inspections of defendants' plant by Investigators of the Food and Drug Administration (FDA) reveal that the facilities, methods, practices, and controls used by said defendants for the manufacture, processing, packing, and holding of fish other than chubs (which fish are, or are intended to be, hot-process smoked fish), are not in conformance with and are not operated and administered in conformity with current good manufacturing practice regulations for the hot-processing of smoked fish as promulgated by FDA, 21 CFR Part 128a, Subpart A, so as to produce for human consumption hot-process smoked fish under sanitary conditions which are adequate to prevent the formation of Clostridium botulinum type E toxin, a dangerous and frequently fatal substance.

7. Illustrative of such deviations from current good manufacturing practice regulations are the following observations made by Food and Drug Administration Investigators:

A. Inspection of February 22 through 26, 1976:

(1) Three batches of hot-process smoked whitefish were heated, cooked, and smoked at temperatures lower than that required by regulations 21 CFR 128a.7(d)(2)(i) and (ii).

(2) The aforesaid three batches of hot-process smoked whitefish contained less water-phase salt after brining than that required by regulations 21 CFR 128a.7(d)(2)(i) and (ii).

(3) Raw fish intended for processing by heating, cooking, and smoking are not stored in separate rooms or facilities prior to such processing, as required by regulation 21 CFR 128a.3(b).

(4) A number of freezers and refrigerators are not equipped with indicating and/or recording thermometers, as required by regulation 21 CFR 128a.4(c).

(5) The majority of ovens for heat-processing fish are not equipped with a point-sensitive, continuous temperature-recording device so as to monitor both the internal temperature of the fish and the ambient temperature within the oven, as required by regulation 21 CFR 128a.7(d)(1).

(6) One batch of hot-process smoked whitefish was not cooled to 38 degrees F. or below within 12 hours after cooking, as required by regulation 21 CFR 128a.7(e)(3).

B. Inspection of July 8 through 11, 1975:

(1) Two batches of hot-process smoked whitefish were heated, cooked, and smoked at temperatures lower than that required by regulations 21 CFR 128a.7(d)(2)(i) and (ii).

(2) The aforesaid two batches of hot-process smoked whitefish contained less water-phase salt after brining than that required by regulations 21 CFR 128a.7(d)(2)(i) and (ii).

(3) Raw fish intended for processing by heating, cooking, and smoking were not stored in separate rooms or facilities prior to such processing, as required by regulation 21 CFR 128a.3(b).

(4) A number of freezers and refrigerators were not equipped with indicating and/or recording thermometers, as required by regulation 21 CFR 128a.4(c).

(5) The majority of ovens for heat-processing fish were not equipped with a point-sensitive, temperature-recording device so as to monitor both the internal temperature of the fish and the ambient temperature within the oven, as required by regulation 21 CFR 128a.7(d)(1).

(6) One batch of hot-process smoked whitefish was not cooled to 38 degrees F. or below within 12 hours after cooking, as required by regulation 21 CFR 128a.7(e)(3).

(7) The temperature of two batches of raw whitefish was not maintained at a temperature of 38 degrees F. or below during the brining process, as required by regulation 21 CFR 128a.7(c)(3)(iv).

8. While at the plant, Food and Drug Administration Investigators collected a number of samples from batches of hot-process smoked whitefish manufactured, processed, packed, held, and subsequently distributed by the defendants. Analysis of the samples by a Food and Drug Administration laboratory reveal the following percentages of water-phase salt (sodium chloride) in the fish in each case less than required by regulation 21 CFR 128a. 7(c)(4):

SAMPLE NUMBER	DATE MANUFACTURED		% WATER-PHASE SALT	
			original analysis	check analysis
76-41-506	2/23-24/76	average-individual fish range-	2.7%	2.9%
			2.3-3.1%	2.5-3.2%
76-41-508	2/23-25/76	average-individual fish range-	1.8%	1.5%
			1.4-2.5%	1.2-2.2%
76-41-509	2/23-26/76	average-individual fish range-	2.0%	1.7%
			1.4-2.8%	1.2-2.5%
76-40-201	7/8-10/75	average-individual fish range-	1.8%	1.9%
			1.5-2.6%	1.5-2.6%
76-40-202	7/8-11/75	average-individual fish range-	2.1%	2.1%
			1.5-2.6%	1.5-2.7%

9. Said articles of food, while held for sale after shipment in interstate commerce, are adulterated within the meaning of 21 U.S.C. 342(a)(4) in that the facilities, methods, practices, and controls used for the manufacture, processing, packing, and holding of said articles do not conform to and are not operated and administered in conformity with current good manufacturing practice in manufacturing, processing,

packing, and holding smoked fish, as prescribed by 21 CFR Part 128a, Subpart A, to assure that said articles may not have been rendered injurious to health.

10. Said defendants violate 21 U.S.C. 331(k) by their acts of manufacturing, processing, packing, and holding said articles of food, in that said acts are done by the defendants while the articles are held for sale after shipment in interstate commerce and result in said articles being adulterated as set forth hereinabove in paragraph 9.

11. The defendants are well aware that their activities are in violation of the law. The defendants' plant has been inspected by Investigators of the Food and Drug Administration on a number of occassions within the period 1973 through July 1975 and violations noted were discussed with the defendant, David Sklar. Two hearings, pursuant to 21 U.S.C. 335, have been held for the defendants, the corporation and David Sklar, during the period April 1973 through November 1973, with respect to deviations from current good manufacturing practice. The defendant, David Sklar has also been warned of the low salt content of the plant's finished hot-process smoked fish by means of results of analyses of samples furnished to him, pursuant to 21 U.S.C. 374(d).

12. Despite the aforesaid inspections, hearings and reports of analyses, the defendants continue to manufacture, process, pack, and hold fish other than chubs, which fish are, or are intended to be hot-process smoked fish, under insanitary conditions resulting in the adulteration of such foods as hereinbefore alleged in paragraph 9.

13. Plaintiff is informed and believes that unless restrained by this Honorable Court the defendants will continue to violate 21 U.S.C. 331(k) in the manner hereinbefore alleged.

WHEREFORE PLAINTIFF PRAYS:

That the defendants, Nova Scotia Food Products Corp., a corporation, and David Sklar and Emanuel Sklar, individuals,

and each and all of their officers, agents, servants, employees, and representatives and any and all persons in active concert or participation with them or any of them be perpetually restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Manufacturing, processing, packing, or holding articles of food, namely, fish other than chubs, which fish are, or are intended to be hot-process smoked fish, after shipment in interstate commerce, unless and until:

I. Facilities, methods, practices, and controls used for the manufacture, processing, packing, and holding of said foods by defendants are established and operated and administered in conformity with current good manufacturing practice as set forth in regulations 21 CFR Part 128a, Subpart A, which shall specifically include the following:

(a) brining fish in such a manner that the final salt (sodium chloride) content of the loin muscle of the finished smoked fish, expressed as percent in the water phase of the loin muscle shall not be less than (1) 3.5 percent if heat-processed at not less than 180 degrees F. for a minimum of 30 minutes or (2) 5.0 percent if heat-processed at not less than 150 degrees F. for a minimum of 30 minutes;

(b) storing all raw fish in separate rooms or facilities from the following processes: receiving; shipping; presmoking operations such as thawing, dressing, brining; drying and smoking;

(c) equipping of each freezer and cold storage compartment with at least (1) an automatic control for regulating temperature, (2) an indicating thermometer so installed as to show accurately the temperature within the compartment, and (3) a recording thermometer so installed as to indicate accurately at all times the temperature within the compartment;

(d) using a point-sensitive, continuous temperature-recording device on each oven to monitor both the internal temperature of the fish and the ambient temperature within the oven;

(e) cooling of the finished product to a temperature of 50 degrees F. or below within 3 hours after cooking, further cooling to a temperature of 38 degrees F. or below within 12 hours after cooking and maintaining 38 degrees F. or below during all subsequent storage and distribution; and

(f) brining of fish in such a manner that the temperature of the fish and brine (1) does not exceed 60 degrees F. at the start of brining, and (2) if between 38 degrees F. and 50 degrees F. at the start of brining, is continuously lowered to 38 degrees F. or below within 12 hours, or (3) if between 50 degrees F. and 60 degrees F. at the start of brining, is continuously lowered to 50 degrees F. or below within 2 hours and to 38 degrees F. or below within the following 10 hours, and (4) does not rise above 38 degrees F. after reaching that temperature or below either prior to or during the brining operation;

II. (a) Defendants' plant and equipment therein are examined by a person, selected by the defendants, who by reason of training and experience is qualified to make inspections of fish-smoking plants to determine if the facilities, methods, controls, and practices conform to and are operated and administered in conformity with current good manufacturing practice as set forth in regulations 21 CFR Part 128a, Subpart A;

(b) said person inspects defendants' facilities, methods, controls, and practices and certifies in writing to the New York District Office of the Food and Drug

Administration that the requirements set forth hereinbefore in Part I of subparagraph A have been met;

(c) defendants report in writing to the New York District Office of the Food and Drug Administration what action they have taken to assure that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and holding of foods, namely fish, are operated and administered in conformity with current good manufacturing practice regulations, 21 CFR Part 128a, Subpart A;

(d) defendants select a testing laboratory which, by reason of equipment and trained and experienced personnel, is qualified to examine smoked fish for percent sodium chloride in the water phase of the loin muscle, and contract with said laboratory to perform such examinations on defendants' brined fish;

(e) defendants provide a schedule for such sodium chloride analyses to the New York District Office of the Food and Drug Administration, said schedule to include the percent, by count, of fish to be tested per batch; and

(f) the Food and Drug Administration notifies defendants in writing that said schedule provides for sufficient numbers of said sodium chloride analyses;

III. The Food and Drug Administration notifies defendants in writing that defendants appear to be in compliance with the requirements set forth hereinbefore in Parts I and II of subparagraph A; and

IV. Duly authorized Food and Drug Administration representatives are granted free access to defendants' plant for the purpose of making such inspections of the plant including all things therein relating to the facilities, methods, controls, and practices used in the manufacture, processing, packing, and holding of raw, in-process and smoked fish as the Food and

COMPLAINT

Drug Administration deems necessary in order to determine that requirements set forth hereinbefore in Parts I and II of paragraph A have been met, the costs of any such inspection to be borne by the defendants at the rate of $8.00 per hour and fraction thereof per representative for inspectional work, $10.00 per hour and fraction thereof per representative for laboratory and analytical work, $0.15 per mile for travel expenses, and $39.00 per day for subsistence expenses where necessary;

B. Manufacturing, processing, packing, or holding at defendants' plant, after compliance has been made with provisions of Parts I through IV of subparagraph A hereinbefore set forth, any articles of food consisting of raw fish intended for hot-process smoking or in-process or finished hot-process smoked fish, while held for sale after shipment in interstate commerce, which acts of manufacturing, processing, packing, or holding result in said articles being adulterated within the meaning of 21 U.S.C. 342(a)(4) in that the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of said articles do not conform to and are not operated or administered in conformity with current good manufacturing practice in manufacturing, processing, packing, and holding smoked fish, as prescribed by 21 CFR Part 128a, Subpart A, to assure that said articles may not have been rendered injurious to health.

That a Temporary Restraining Order be granted, after plaintiff has given notice to the defendants or their attorney, restraining the defendants and each and all of their officers, agents, servants, employees, and representatives and any and all persons in active concert or participation with them or any of them, for 10 days as prayed hereinbefore, since as shown by the attached affidavits immediate and irreparable injury and damage will result to the plaintiff and the consuming public.

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COMPLAINT

That the defendants and each and all of their officers, agents, servants, employees, and representatives and any and all persons in active concert or participation with them or any of them be enjoined and restrained as herein prayed during the pendency of this action, and that the plaintiff be granted judgment for its costs herein, and for such other and further relief as to the Court may seem just and proper.

Dated: Brooklyn, New York
April 7, 1976

DAVID G. TRAGER
UNITED STATES ATTORNEY
Attorney for Plaintiff

By: DAVID W. McMORROW

DAVID W. McMORROW
Assistant U. S. Attorney

OF COUNSEL:

Arnold I. Friede
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U.S. Department of Health, Education, and Welfare
Office of the General Counsel
Food and Drug Division
Rockville, Maryland 20852

AMENDED ANSWER OF DEFENDANTS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., a corporation, and DAVID SKLAR and EMANUEL SKLAR, individuals,

Defendants.

X----------X

CIVIL ACTION
No. 76-C-647

(Judge Dooling)

AMENDED
ANSWER

Defendants, by their attorneys, Aranow, Brodsky, Bohlinger, Benetar & Einhorn, for their answer herein, allege:

FIRST DEFENSE

1. Deny each and every allegation contained in paragraph "1" except admit that this action is purportedly brought under 21 U.S.C. 332(a).

2. Admit the allegations contained in paragraph "2".

3. Admit the allegations contained in paragraph "3".

4. Admit the allegations contained in paragraph "4".

5. Admit the allegations contained in paragraph "5".

6. Deny each and every allegation contained in paragraph "6", except admit that in certain respects whitefish processed by the defendant corporation is not processed in full compliance with the cited regulation.

AMENDED ANSWER OF DEFENDANTS

7. Deny each and every allegation contained in paragraph "7", except allege they are without knowledge or information sufficient to form a belief as to the truth of the allegations as to the observations of various inspectors, and state as follows as to the specific allegations of said paragraph:

A. (1) Admit.

A. (2) Admit.

A. (3) Admit that there is no separate storage room but deny that such is required by 21 CFR 128a.3(b).

A. (4) Deny, except admit as to recording thermometers and allege that all devices required by 21 CFR 128a.4(c) have now been installed.

A. (5) Admit, and allege that it is impossible to utilize such devices on all but one of the ovens employed by defendants in their operations which oven is properly equipped with such a device.

A. (6) Deny, except admit a temporary rise in temperature to permit employees to enter the room to pack the processed fish.

B. (1) Admit.

B. (2) Admit.

B. (3) Admit that there is no separate storage room but deny that such is required by 21 CFR 128a.3(b).

B. (4) Deny, except admit as to recording thermometer and allege that all such devices required by 21 CFT 128a.4(c) have now been installed.

B. (5) Admit, and allege that it is impossible to utilize such devices on all but one of the ovens em-

ployed by defendants in their operations which even is properly equipped with such a device.

B. (6) Deny, except admit a temporary rise in temperature to permit employees to enter the room to pack the processed fish.

B. (7) Deny.

8. Deny each and every allegation contained in paragraph "8", except admit that certain specimens were collected and allege that they are without knowledge or information sufficient to form a belief as to the tests and the specific results referred to.

9. Deny each and every allegation contained in paragraph "9".

10. Deny each and every allegation contained in paragraph "10".

11. Deny each and every allegation contained in paragraph "11".

12. Deny each and every allegation contained in paragraph "12".

13. Deny each and every allegation contained in paragraph "13".

SECOND DEFENSE

14. The complaint fails to state a claim upon which relief may be granted.

AMENDED ANSWER OF DEFENDANTS

THIRD DEFENSE

15. The products sold by defendants are not "adulterated" within the meaning of the statute.

FOURTH DEFENSE

16. There is no reasonable possibility that the products sold by defendants may be injurious to health.

FIFTH DEFENSE

17. The regulations are in excess of the statutory authority of the FDA and are, at most, non-binding guidelines.

SIXTH DEFENSE

18. The requirement of a separate storage room as set forth in 21 CFR 128a.3(b) is not a mandatory requirement of the GMP and is phrased in terms of "should" rather than "shall". Notwithstanding that it is not a mandatory requirement of the GMP, defendants are in the process of obtaining necessary financing to construct a plan at a cost of approximately $500,000 which will contain such a separate room.

SEVENTH DEFENSE

19. All refrigerators utilized by defendants are now equipped with automatic temperature controls, indicating thermometers and recording thermometers as required by 21 CFR 128a.(c).

AMENDED ANSWER OF DEFENDANTS

EIGHT DEFENSE

20. The temperature of all processed fish is reduced to 38°F within 12 hours of processing as required by 21 CFR 128a.7(e)(3). Any rise in temperature results from the fact that the room temperature must be temporarily raised to 50°F to permit the fish to be packed as employees refuse to work in a 38°F room. The fish remain in the 50°F room for a maximum of 3 to 4 hours during which the temperature of the fish does not reach 50°F but remains lower. Following packing the 38°F temperature is achieved promptly. No reasonably possible danger to health arises from this procedure.

NINTH DEFENSE AND FIRST COUNTERCLAIM

21. The requirement of 21 CFR 128a.7(d)(1) requiring point-sensitive, continuous temperature recording devices is arbitrary, capricious, unreasonable and confiscatory. Sucy equipment is not reasonably required to achieve the statutory objectives.

22. The ovens currently in use by defendants and many members of the industry do not contain the equipment called for, nor is it feasible or even possible to install such equipment in those ovens. New ovens with such equipment cost approximately $65,000 each and the immediate installation of such ovens is beyond the economic capability of most industry members and of the defendants. Defendants have recently installed one such oven and intend, to the extent financing permits, to replace all existing ovens with new ones over the next five years.

23. The strict imposition of the requirement would drive defendants and other members of the industry out of business without any corresponding benefit with respect to the protection of the consuming public.

24. Accordingly, this provision of the regulations should be declared null and void and of no force and effect. Alternatively, the Court should stay the effective date thereof for a period of five (5) years to permit defendants to obtain replacement equipment.

TENTH DEFENSE AND SECOND COUNTERCLAIM

25. The Good Manufacturing Practice Regulations (GMP) found in 21 CFR 128a. provide for two alternative methods for the hot processing of smoked whitefish:

(a) Brining with a water phase salt content (as measured by the interior loin muscle) of 3.5% and cooking of the fish at 180°F for 30 minutes; or

(b) Brining with a water phase salt content (as measured by the interior loan muscle) of 5.0% and cooking of the fish at 150°F for 30 minutes.

26. Preparation of hot smoked whitefish by either of these methods produces a product that is unacceptable and unusable in defendants' market place.

27. In or about 1969, when the GMP was proposed, members of the industry advised the FDA on several occasions and by formal written submissions that hot smoked whitefish of a commercially acceptable nature could not be produced in accordance with the proposed GMP. It was also suggested to FDA that the proposed GMP was unnecessary

to the protection of public health and was deficient in numerous respects in that it failed to provide adequate protection against other hazards.

28. In or about 1971, a petition was submitted to FDA by the National Marine Fisheries Service on behalf of the industry seeking approval of a food additive provision permitting the use of nitrites in the processing of hot smoked whitefish (the Whitefish Petition). The Whitefish Petition remains pending.

29. Scientific data available to the FDA at the time of the adoption of GMP, at the time of the Whitefish Petition and developed at later dates indicates:

(a) that the use of nitrites in the processing of whitefish is safe and that carcinogenic agents are not present in whitefish processed with nitrites;

(b) that safe and commercially acceptable hot smoked whitefish can be produced by use of nitrites of 100-200 ppm, in conjunction with a water phase salt content of 3.0 to 3.5 percent heated to 150°F for 30 minutes;

(c) that even the standards imposed by the GMP do not provide protection against certain potential hazards.

30. Additional research in all relevant areas is currently under way and will be completed in approximately one year. The industry involved has funded this research to the extent of $80,000.

31. The adoption of the GMP and the failure of the FDA to act upon the Whitefish Petition have placed

defendants and other processors of hot smoked whitefish in the position of not being able to prepare a marketable product and still comply with the GMP.

32. The adoption of the GMP was unreasonable, arbitrary, capricious, unfair and confiscatory and the GMP was not supported by the administrative record. This is true not only in view of the then available scientific evidence but becomes even clearer when the additional scientific data generated since 1969 is considered.

33. The failure of the FDA to act upon the Whitefish Petition is unreasonable, arbitrary, capricious, unfair and confiscatory.

34. Additionally, the FDA has failed to consider or give adequate weight to a number of additional factors which adequately protect the public against the hazards involved. These include: inspection of incoming raw material and the rejection of poor quality products; use of chlorinated water for washing the fish prior to processing; proper refrigeration of the product at all times; proper packaging; proper distribution of the product; education of vendors and the consuming public as to the perishable nature of the product, including the need for continuous refrigeration and prompt consumption. All of these items are currently being implemented by defendants and other members of the industry.

35. Enforcement of the current GMP requirements would drive defendants and other members of the industry out of business without any rational or legal basis therefor.

36. As a result of the foregoing, the GMP should be declared null and void and of no force and effect. Alternatively, this Court should stay the enforcement of the GMP on the following conditions, or on such other conditions as it deems just and proper:

(a) that all hot smoked whitefish be processed at an average salt level of 3.0-3.5% at 150°F for 30 minutes with nitrites of 100-200 ppm;

(b) that the FDA receive and evaluate all existing scientific data plus the results of the research currently in progress and based thereon reconsider de novo the existing GMP and the pending Whitefish Petition.

ELEVENTH DEFENSE

37. The granting of injunctive relief against defendants would be unfair, inequitable and unjust.

38. Injunctive relief is not reasonably required in the public interest.

39. The granting of injunctive relief solely against defendants would be unfair and inappropriate in view of the fact that the practices complained of by plaintiff are industry-wide practices. The Court should not permit selective enforcement which would place defendants at a great disadvantage vis a vis the rest of the industry.

WHEREFORE, defendants request judgment (a) dismissing the complaint, (b) granting appropriate relief on their counterclaims, and (c) granting such other, further and

different relief as may be just and proper in the premises.

ARANOW, BRODSKY, BOHLINGER,
BENETAR & EINHORN

By: Joseph H. Einstein
Joseph H. Einstein
A Member of the Firm
Attorneys for Defendants
Office & P.O. Address
469 Fifth Avenue
New York, N.Y. 10017
(212) 889-1470

DEFENDANTS' REQUEST FOR PRODUCTION OF DOCUMENTS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., a corporation, and DAVID SKLAR and EMANUEL SKLAR, individuals,

Defendants.

X----------X

CIVIL ACTION
No. 76-C-647

(Judge Dooling)

DEFENDANTS' REQUEST FOR DOCUMENTS

SIRS:

PLEASE TAKE NOTICE, that defendants hereby request production of the following documents:

1. All Establishment Inspection Endorsements and Inspectional Observations prepared by the FDA with respect to all persons, firms or corporations engaged in the processing of smoked whitefish during the period January 1, 1970 to date.

2. The complete administrative record with respect to the GMP set forth in 21 CFR 128a, including but not limited to all opinions and recommendations with respect thereto.

3. The complete administrative record with respect to the Whitefish Petition which was submitted to the FDA in or about 1971, including but not limited to all opinions and recommendations with respect thereto.

DEFENDANTS' REQUEST FOR PRODUCTION OF DOCUMENTS

4. All books, records, documents, reports, scientific data and other writings:

a) Relating to or concerning the presence of botulinum spores or toxin in whitefish (either before or after processing) and the effects thereon of (1) salt, (2) heat, (3) nitrites, (4) washing, (5) refrigeration, or (6) any other factors relevant to the outgrowth of spores or the creation of toxins.

b) Relating to or concerning (1) the ability of persons, firms or corporations engaged in the processing of whitefish to comply with the requirements of 21 CFR 128a either in general or as to specific items and (2) the effects upon and commercial acceptability of whitefish prepared in accordance with the requirements of 21 CFR 128a.

5. All records and reports of any instances of butulism illness or death resulting from the consumption of hot smoked whitefish.

Dated: New York, N.Y.
April 29, 1976.

Yours, etc.

ARANOW, BRODSKY, BOHLINGER, BENETAR & EINHORN

By Joseph H. Einstein
Joseph H. Einstein
A Member of the Firm
Office & P.O. Address
469 Fifth Avenue
New York, N.Y. 10017
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TO:

DAVID G. TRAGER, ESQ.
United States Attorney
Eastern District of New York
Federal Courthouse
225 Cadman Plaza East
Brooklyn, New York

ANSWER OF INTERVENOR NATIONAL FISHERIES INSTITUTE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

X----------X

UNITED STATES OF AMERICA,

Plaintiff

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., a corporation, and DAVID SKLAR and EMANUEL SKLAR, individuals,

Defendants.

X----------X

CIVIL ACTION
No. 76-C-647

(Judge Dooling)

ANSWER OF INTERVENOR NATIONAL FISHERIES INSTITUTE

Intervenor National Fishers Institute ("NFI"), by its attorneys Kleinfeld, Kaplan and Becker, for its answer herein, alleges:

FIRST DEFENSE

1. Smoked whitefish which do not comply with the time, temperature and salt content requirements of the smoked fish good manufacturing practice ("GMP") regulations are not "adulterated" within the meaning of the statute.

SECOND DEFENSE

2. There is no reasonable possibility that smoked whitefish which are processed in accordance with present industry practice may be injurious to health.

THIRD DEFENSE

3. The smoked fish GMP regulations are in excess of the statutory authority of the FDA.

FOURTH DEFENSE

4. The smoked fish GMP regulations are not legal requirements but, at most, non-binding guidelines

FIFTH DEFENSE AND FIRST COUNTERCLAIM

5. The smoked fish GMP regulations provide for two alternative methods for the hot processing of smoked whitefish:

(a) Brining with a water phase salt content (as measured by the interior loin muscle) of 3.5% and cooking of the fish at 180°F for 30 minutes; or

(b) Brining with a water phase salt content (as measured by the interior loan muscle) of 5.0% and cooking of the fish at 150°F for 30 minutes.

6. Preparation of hot smoked whitefish by either of these methods produces a product that is unacceptable and unusable in the market place in major areas of the country in terms of smoked whitefish consumption.

7. In or about 1969, when the GMP was proposed, NFI and individual members of the industry advised the FDA on several occasions and by formal written submissions that hot smoked whitefish of a commercially acceptable nature could not be produced in accordance with the proposed GMP. It was also suggested to FDA that the proposed GMP was unnecessary to the protection of public health and was deficient in numerous respects in that it failed to provide adequate protection against other hazards.

8. In or about 1971, a petition was submitted to FDA by the National Marine Fisheries Service on behalf of the industry seeking approval of a food additive provision permitting the use of nitrites in the processing of hot smoked whitefish (the Whitefish Petition). The Whitefish Petition remains pending.

9. Scientific data available to the FDA at the time of the adoption of GMP, at the time of the Whitefish Petition and developed at later dates indicates:

(a) that the use of nitrites in the processing of whitefish is safe and that carcinogenic agents are not present in whitefish processed with nitrites;

(b) that safe and commercially acceptable hot smoked whitefish can be produced by use of nitrites of 100-200 ppm, in conjunction with a water phase salt content of 3.0 to 3.5 percent heated to 150°F for 30 minutes;

(c) that even the standards imposed by the GMP do not provide protection against certain potential hazards.

10. Additional research in all relevant areas is currently under way and will be completed in approximately one year. The industry, through NFI, involved has funded this research to the extent of $80,000.

11. The adoption of the GMP and the failure of the FDA to act upon the Whitefish Petition have placed processors of hot smoked whitefish in the position of not being able to prepare a marketable product and still comply with the GMP.

12. The adoption of the GMP was unreasonable, arbitrary, capricious, unfair and confiscatory and the GMP was not supported by the administrative record. This is true not only in view of the then available scientific evidence but becomes even clearer when the additional scientific data generated since 1969 is considered.

13. The failure of the FDA to act upon the Whitefish Petition is unreasonable, arbitrary, capricious, unfair and confiscatory.

14. Additionally, the FDA has failed to consider or give adequate weight to a number of additional factors which adequately protect the public against the hazards involved. These include: inspection of incoming raw material and the rejection of poor quality products; use of chlorinated water for washing the fish prior to processing; proper refrigeration of the product at all times; proper packaging; proper distribution of the product; education of vendors and the consuming public as to the perishable nature of the product, including the need for continuous refrigeration and prompt consumption. All of these items are currently being implemented by members of the industry.

ANSWER OF INTERVENOR NATIONAL FISHERIES INSTITUTE

15. Enforcement of the current GMP requirements would drive members of the industry out of business without any rational or legal basis therefor.

16. As a result of the foregoing, the GMP should be declared null and void and of no force and effect. Alternatively, this Court should stay the enforcement of the GMP on the following conditions, or on such other conditions as it deems just and proper:

(a) that all hot smoked whitefish be processed at an average salt level of 3.0-3.5% at 150°F for 30 minutes with nitrites of 100-200 ppm;

(b) that the FDA receive and evaluate all existing scientific data plus the results of the research currently in progress and based thereon reconsider de novo the existing GMP and the pending Whitefish Petition.

WHEREFORE, NFI requests judgment (a) granting appropriate relief on its counterclaim and (b) granting such other, further and different relief as may be just and proper in the premises.

KLEINFELD, KAPLAN & BECKER

By:

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PLAINTIFF'S REPLY TO COUNTERCLAIMS OF DEFENDANTS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

- X

UNITED STATES OF AMERICA,

Plaintiff,

v.

NOVA SCOTIA FOOD PRODUCTS CORP., a corporation and DAVID SKLAR and Emanuel Sklar, individuals,

Defendants.

- X

REPLY TO COUNTERCLAIMS

Civil Action
No. 76-C-647

Plaintiff, United States of America, appearing by its attorney, David G. Trager, United States Attorney for the Eastern District of New York, in reply to defendants' counterclaims avers as follows:

REPLY TO FIRST COUNTERCLAIM

FIRST DEFENSE

Defendants' first counterclaim fails to state a claim upon which relief may be granted.

SECOND DEFENSE

Replying specifically to the allegations of the numbered paragraphs of the first counterclaim, plaintiff admits, denies, and alleges as follows:

Para. No. 21. Denied. Assurance that the time-temperature requirements of 21 CFR 128a.7(d)(2) are met can only be attained by the use of the point-sensitive, continuous temperature recording device required by 21 CFR 128a.7(d)(1).

Para. No. 22. Plaintiff admits that all except one of the ovens currently in use by defendants do not contain the required temperature recording devices but denies that it

is not feasible or possible to install such equipment in the said ovens. Plaintiff is without knowledge and information sufficient to form a belief as to the cost of new ovens but alleges that such cost is irrelevant, since the ovens currently used by the defendants which lack such equipment are brick ovens on which the required devices can be installed at a reasonable cost. Plaintiff is without knowledge and information sufficient to form a belief as to defendants' future plans for the replacement of said ovens.

Para. No. 23. Denied. The point-sensitive, continuous-temperature recording device required by 21 CFR 128a.7(d)(1) protects the consuming public from the risk of poisoning from C. botulinum Type E, since it accurately measures whether the time-temperature requirements of 21 CFR 128a. 7(d)(2) are being met, which times and temperatures, together with the required salt content, are necessary to avoid the risks of such poisoning.

Para. No. 24. Denied.

Any allegations not specifically admitted or qualified are denied.

REPLY TO SECOND COUNTERCLAIM

FIRST DEFENSE

Defendants' second counterclaim fails to state a claim upon which relief may be granted.

SECOND DEFENSE

Replying specifically to the allegations of the numbered paragraphs of the second counterclaim, plaintiff admits, denies and alleges as follows:

Para. No. 25. These are statements and conclusions of law and require no answer.

PLAINTIFF'S REPLY TO COUNTERCLAIMS OF DEFENDANTS

Para. No. 27. Plaintiff admits that it was advised by industry that hot-smoked whitefish of a commercially acceptable nature could not be produced in accordance with the proposed good manufacturing practice regulations for the hot-processing of smoked fish. Plaintiff is without knowledge or information sufficient to form belief as to the allegations of the second sentence.

Para. No. 28. Plaintiff admits the allegations of the first sentence. Plaintiff admits that the petition is pending before the Agency but alleges that the petitioner, National Marine Fisheries Service, was informally advised during 1973 that the petition would not be granted and should be withdrawn, and that the petitioner refused to withdraw the petition but agreed that it remain pending.

Para. No. 29. Denied.

Para. No. 30. Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

Para. No. 31. Denied.

Para. No. 32. Denied.

Para. No. 33. Denied.

Para. No. 34. Denied.

Para. No. 35. Denied.

Para. No. 36. Denied.

Para. No. 37. Denied.

Para. No. 38. Denied.

PLAINTIFF'S REPLY TO COUNTERCLAIMS OF DEFENDANTS

Para. No. 39. Denied.

Any allegations not specifically admitted or qualified are denied.

THIRD DEFENSE

This court lacks subject matter jurisdiction over defendants counterclaim in that, inter alia, the propriety of the use of nitrites in the processing of hot-smoked whitefish pursuant to the petition submitted by the National Marine Fisheries Services is a matter over which the Food and Drug Administration has exercised primary jurisdiction under Section 409 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 348, and over which this Court lacks jurisdiction, because exclusive jurisdiction for review of the Agency's action is approving or refusing to approve such a petition lies in a Court of Appeals pursuant to 21 U.S.C. 348(g).

DAVID G. TRAGER
United States Attorney
Eastern District of New York
Attorney for Plaintiff

By David W. McMorrow
David W. McMorrow
Assistant U. S. Attorney

AFFIDAVIT OF ARNOLD ISAAC FRIEDE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------x

UNITED STATES OF AMERICA,

Plaintiff,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., a corporation, and DAVID SKLAR and EMANUEL SKLAR, individuals,

Defendants.

----------x

CIVIL ACTION NO. 76-C-647

AFFIDAVIT

STATE OF MARYLAND)
COUNTY OF MONTGOMERY)

ARNOLD ISAAC FRIEDE, being first duly sworn, deposes and says:

1. I am employed as an attorney with the Office of the General Counsel, Department of Health, Education, and Welfare, Food and Drug Division, and have been assigned to assist the United States Attorney for the Eastern District of New York in the trial of the above-captioned action.

2. In connection with the preparation of this matter for trial and also pursuant to defendants' request for production of the administrative record upon which the smoked fish Good Manufacturing Practice (GMP) regulations involved in this action was based, I requested that Agency personnel secure the factual material that was considered by the Food and Drug Administration at the time the Agency determined to adopt the regulations.

AFFIDAVIT OF ARNOLD ISAAC FRIEDE

3. This material, submitted herewith, which is indexed in the attached EXHIBIT A, consists generally of: (1) the documents compiled by the Food and Drug Administration Hearing Clerk in the rulemaking proceeding, including the Federal Register document that proposed the promulgation of the regulations, copies of all comments received in response to the proposal, including that of defendant Nova Scotia Food Products Corp., and the Federal Register document promulgating the final regulations [TAB A]; (2) copies of reports submitted to the Food and Drug Administration by researchers who were under contract with the Agency to conduct studies on the incidence and hazard of C. botulinum Type E in smoked fish and processing parameters which would minimize those hazards [TAB B(1) - B(12)]; (3) copies of reports provided to the Food and Drug Administration by the Bureau of Commercial Fisheries describing general guidelines for process and sanitation control necessary to minimize risks associated with smoked fish [TAB C(1) and (2)]; (4) copies of studies prepared by Food and Drug Administration employees in connection with the feasibility of compliance with the processing parameters later embodied in the GMPs and the market acceptability of smoked fish so produced [TAB D(1) - (4)]; (5) a copy of a summary of a meeting held by the Food and Drug Administration with scientists to discuss processing parameters for smoked fish [TAB E]; and (6) copies of scientific articles

AFFIDAVIT OF ARNOLD ISAAC FRIEDE

which provided information upon which the regulations were based, divided into the following general topics:

I. Bibliography prior to October 23, 1969

A. Incidence of Clostridium botulinum and botulism [TAB F(1) - (72)]

B. Cooking-Smoking Times and Temperatures [TAB G(1) - (10)]

C. Effects of Salt [TAB H(1) - (7)]

D. Storage Temperatures [TAB I]

E. Botulism Publications concerning two or more of the above subject areas or related areas [TAB J(1) - (23)]

II. Bibliography between October 23, 1969 and November 13, 1970

A. Incidence of Clostridium botulinium and botulism [TAB K(1) and (2)]

B. Cooking-Smoking Times and Temperatures [TAB L]

Arnold Isaac Friede

ARNOLD ISAAC FRIEDE
Attorney, Office of the
Chief Counsel
United States Food and
Drug Administration

Subscribed and sworn to before me, a Notary Public, this 14th day of May, 1976.

Joan P. Woodfield

Notary Public

JOAN P. WOODFIELD NOTARY PUBLIC MONTGOMERY MD.

My commission expires 7-1-77.

EXHIBIT A TO FRIEDE AFFIDAVIT - LIST OF DOCUMENTS

INDEX

TAB A Documents Compiled by the Food and Drug Administration Hearing Clerk in the Rulemaking Proceeding

TAB B (1) Quarterly Report, Contract No. FDA-63-77 (Neg.) Covering June, July, and August, 1963

(2) Quarterly Report, Contract No. FDA-63-77 (Neg.) Covering September through December, 1963

(3) Third Quarterly Report, Contract No. FDA-63-77 (Neg.) Covering the period January through March, 1964

(4) Final Report to the Food and Drug Administration, HEW, on Contract No. FDA 63-77 (Neg.) from the University of Wisconsin, June 1, 1964

(5) First Quarterly Report, Contract No. FDA-64-44 (Neg.) Covering June, July and August, 1964

(6) Second Quarterly Report, Contract No. FDA-64-44 (Neg.) Covering September, October and November, 1964

(7) Third Quarterly Report, Contract No. FDA 64-44 (Neg.) Covering December, 1964, through February, 1965

(8) Quarterly Report, Contract No. FDA 64-44 (Neg.) July 1 through September 30, 1965

(9) Quarterly Report, Contract No. FDA 64-44 (Neg.) January 1 through March 31, 1966

(10) Quarterly Report, Contract No. FDA 64-44 (Neg.) April 1 through June 30, 1966

(11) Annual Report, Contract No. FDA 64-44 (Neg.) June 1, 1964 through June 30, 1965

(12) Quarterly Report, Contract No. 64-44 (Neg.) July 1 through September 30, 1966

TAB C (1) Smoked-Fish Processing and Handling--Interim Guidelines for Process and Sanitation Control (Draft 4), October 5, 1964

(2) Guidelines for the Processing of Hot-Smoked Fish (Draft 3), March 30, 1967

EXHIBIT A TO FRIEDE AFFIDAVIT - LIST OF DOCUMENTS

INDEX (Cont.)

TAB D (1) A Study of Methods for Hanging Fish During the Smoking Process, Richard R. Klug, FDA

(2) A Study of Methods for Hanging Fish During the Smoking Process, Phase Number Two of the Commercial Study, Richard R. Klug, FDA

(3) A Study of Methods for Hanging Fish During the Smoking Process, Phase 3 of the Commercial Study, Richard R. Klug, FDA

(4) A Study of Methods for Hanging Fish During the Smoking Process, Phase 4 of the Commercial Study, Richard R. Klug, FDA

TAB E Summary of the Meeting to Review the F.D.A. Smoked Fish Compliance Program Held at the University of Wisconsin, July 11, 1968

TAB F (1) R. L. Whittaker, R. B. Gilbertson, Et. al., "Botulism Type E, Report of Eight Simultaneous Cases," Annals of Internal Medicine, V. 61, No. 3, September 1964.

(2) P. J. Pace, E. R. Krumbiegel, et. al., "The Distribution of Cl. Botulinum Types in Fish Processed by Smoking Plants of the Milwaukee Area," Botulism, 1966, Chapman and Hall, Ltd., London.

(3) H. O. Pedersen, "On Type E Botulism," Symposium on Food Microbiology and Public Health, Paper XVI.

(4) B. J. Osheroff, G. G. Slocum, et. al., "Status of Botulism in the United States," Public Health Reports, V. 79, No. 10, October 1964.

(5) D. F. Ohye, W. J. Scott, "Studies In The Physiology of Clostridium Botulinum Type E," Journal Biological Science, V. 10, August 1959, p. 85-94.

(6) M. W. Presnell, J. J. Meiscier, et. al., "Clostridium botulinum in Marine Sediments and in the Oyster (Crassostrae virginica) from Mobile Bay," Journal of Applied Microbiology, May 1967, p. 668-669.

EXHIBIT A TO FRIEDE AFFIDAVIT - LIST OF DOCUMENTS

(7) C. E. Dolman, H. Chang, et. al., "Fish-Brone and Type E Botulism, Two Cases Due to Home-Pickled Herring," Canadian Journal of Public Health, V. 41, No. 6, June 1950, p. 215-228.

(8) C. E. Dolman, H. Chang, "The Epidemiology and Pathogenesis of Type E and Fish-Borne Botulism," Canadian Journal of Public Health, V. 44, No. 7, July 1953, p. 231-244.

(9) C. E. Dolman, H. Iida, "Type E Botulism: Its Epidemiology, Prevention and Specific Treatment," Canadian Journal of Public Health, V. 54, No. 7, July 1963, p. 293-308.

(10) C. E. Dolman, D. E. Kerr, "Botulism in Canada, with Report of a Type E Outbreak at Nanaimo, B.C.," Canadian Journal of Public Health, V. 38, p. 48-57.

(11) Y. Nakamura, H. Iida, et. al., "Type E Botulism in Hokkaido, Japan," Japanese Journal of Medical Science and Biology, 9, 1956, p. 45-58.

(12) J. B. Gunnison, J. R. Cummings, et. al., "Clostridium Botulinum Type E," Proceedings of the Society of Experimental Biological Medicine, 35, 1936, p. 279-280.

(13) I. Kleeman, S. Frant, "Food Poisoning Outbreaks Involving Smoked Fish--Their Epidemiology and Control," American Journal of Public Health, V. 32, No. 2, February 1942, p. 151-158.

(14) C. E. Dolman, "Human Botulism in Canada," Canadian Medical Association Journal, June 1953, p. 538-543.

(15) P. J. Pace, E. R. Krumbiegel, et. al., "Demonstration and Isolation of Clostridium botulinum Types from Whitefish Chubs, Collected at Fish Smoking Plants of the Milwaukee Area," Journal of Applied Microbiology, July 1967, p. 877-884.

(16) T. L. Bott, J. Johnson, Jr., et. al., "Possible Origin of the High Incidence of Clostridium botulinum Type E in an Inland Bay (Green Bay of Lake Michigan)," Journal of Applied Microbiology, May 1968, p. 154-157.

EXHIBIT A TO FRIEDE AFFIDAVIT - LIST OF DOCUMENTS

(17) H. Iida, Y. Nakamura, et. al., "Additional Type E Botulism Outbreaks in Hokkaido, Japan," Japanese Journal of Medical Science and Biology, 11, 1958, p. 215-222.

(18) B. Q. Ward, B. J. Carroll, et. al., "Survey of the U.S. Atlantic Coast and Estuaries from Kay Largo to Staten Island for the Presence of Clostridium botulinum," Journal of Applied Microbiology, July 1967, p. 964-965.

(19) B. Q. Ward, B. J. Carroll, et. al., "Survey of the U.S. Gulf Coast for the Presence of Clostridium botulinum," Journal of Applied Microbiology, May 1967, p. 629-636.

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PLAINTIFF'S REPLY TO COUNTERCLAIM OF INTERVENOR NATIONAL FISHERIES INSTITUTE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. NOVA SCOTIA FOOD PRODUCTS CORP, a corporation and DAVID SKLAR and EMANUEL SKLAR, individuals, Defendants.	CIVIL ACTION NO. 76-C-647 REPLY TO COUNTERCLAIM OF DEFENDANT-INTERVENOR NATIONAL FISHERIES INSTITUTE

Plaintiff, United States of America, appearing by its attorney David G. Trager, United States Attorney for the Eastern District of New York, in reply to defendant-intervenor National Fisheries Institute's counterclaims avers as follows:

REPLY TO FIRST COUNTERCLAIM

FIRST DEFENSE

Defendant-intervenor's first counterclaim fails to state a claim upon which relief may be granted.

SECOND DEFENSE

Replying specifically to the allegations of the numbered paragraphs of the first counterclaim, plaintiff admits, denies and alleges as follows:

Para. No. 5. These are statements and conclusions of law and require no answer.

Para. No. 6. Denied.

Para. No. 7. Plaintiff admits that it was advised by industry that hot-smoked whitefish of a commercially acceptable nature could not be produced in accordance with the proposed good manufacturing practice regulations for the hot-processing of smoked fish. Plaintiff is without knowledge

or information sufficient to form belief as to the allegations of the second sentence.

Para. No. 8. Plaintiff admits the allegations of the first sentence. Plaintiff admits that the petition is pending before the Agency but alleges that the petitioner, National Marine Fisheries Service, was informally advised during 1973 that the petition would not be granted and should be withdrawn, and that the petitioner refused to withdraw the petition but agreed that it remain pending.

Para. No. 9. Denied.

Para. No. 10. Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the allegations in this paragraph.

Para. No. 11. Denied.

Para. No. 12. Denied.

Para. No. 13. Denied.

Para. No. 14. Denied.

Para. No. 15. Denied.

Para. No. 16. Denied.

Para. No. 17. Any allegations not specifically admitted or qualified are denied.

SECOND DEFENSE

The propriety of the use of nitrites in the processing of hot-smoked whitefish pursuant to the petition submitted by the National Marine Fisheries Services is a matter over which the Food and Drug Administration has exercised primary jurisdiction under Section 409 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 348, and over which this Court lacks jurisdiction, because exclusive jurisdiction for review of the Agency's action in approving or refusing to approve such a petition lies in a Court of Appeals pursuant to 21 U.S.C. 348(g).

DAVID G. TRAGER
United States Attorney
Eastern District of New York

By: S/
DAVID W. McMORROW
Assistant United States Attorney

STENOGRAPHER'S TRANSCRIPT OF TRIAL FROM MAY 17, 1976 THROUGH MAY 19, 1976

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

----------x

UNITED STATES OF AMERICA, :

-against- : 76-C-647

NOVA SCOTIA FOOD PRODUCTS, :

Defendant. :

----------x

United States Courthouse
Brooklyn, New York

May 17, 1976
9:15 o'clock A.M.

B e f o r e :

HONORABLE JOHN F. DOOLING, JR., U.S.D.J.

JOSEPH BARBELLA
OFFICIAL COURT REPORTER

STENOGRAPHER'S TRANSCRIPT OF TRIAL FROM MAY 17, 1976 THROUGH MAY 19, 1976

Appearances:

DAVID G. TRAGER, ESQ.
United States Attorney
for the Eastern District of New York

BY: DAVID MC MORROW, ESQ.
Assistant U.S. Attorney

-and-

ARNOLD I. FRIEDE, ESQ.
FORREST T. PATTERSON, ESQ.
Office of the Chief Counsel, Food & Drug Adminis.

JOSEPH H. EINSTEIN, ESQ.
-and-
RICHARD S. MOREY, ESQ.
Attorneys for Defendant

THE COURT: Yes, sir?

MR. EINSTEIN: If your Honor please, my name is Joseph Einstein. I represent the defendants in this action. I would like to introduce Mr. Richard Morey of the firm of Kleinfield, Kaplan & Becker of Washington, D.C. Mr. Morey is a member of the Bar of the State of New York and of the District. I move his admission to the Bar for this Court for the purposes of this case.

THE COURT: Is there any objection?

MR. MC MORROW: No objection.

MR. EINSTEIN: I think the first order of business, your Honor, is Mr. Morey's application on behalf of the National Fisheries Institute for leave to intervene.

THE COURT: Yes.

MR. MOREY: Your Honor, the National Fisheries Institute has moved to intervene in this matter under Rule 24. I believe that we meet the standards of that rule, and our intervention should be permitted. This intervention was done because the Association feels it has vital interest at stake in this matter. There are definitely common questions of law and fact which affects other members of the National Fisheries Institute, as I indicated in my motion papers we feel

likely to be the predominant questions in this case. 4
Further, under the rule, our intervention will not either delay this matter or prejudice the other parties. The defendants are in favor of our intervention. We have worked quite closely with the defendant in the preparation of this case. We plan to present a common case with them. We expect that with possible rare exceptions that only one of us would examine any given witness, so our intervention would in no way delay or impede the proceeding of this case. I also think that there are strong precedents for our intervention in this situation. The law is quite clear that associations have standing to sue on behalf of their members. There are several D.C. circuit cases on this. There was the American Federation of Government Employees v. Payne, 436 F. 2d 882; National Automatic Laundry and Cleaning v. Schultz at 443 F. 2d 889. This is a Food & Drug case with an opinion of the District Court in Delaware. Abbott Laboratories v. Celebrese, this went to the Supreme Court, but only the District Court considered the question of the association's standing to sue on behalf of its members. It was not raised by the parties in the appellate proceedings. In addition, there is a recent Second Circuit case involving intervention by an association

on behalf of its members, and a regulation on which the members were interested was under challenge. This is New York Public Interest's research group v. Regents of the University of the State of New York. I would like to present a copy of that to the Court (handing).

Particularly, I refer to the language on page 352, where this per curiam opinion states with respect to the Association of Pharmacists. We hold it has a sufficient interest to permit to intervene, since the validity of a regulation from which a member's benefit is challenged. The only difference here, there is some question of whether our members benefit from the regulation at issue, but I think it is a very clear precedent in favor of our intervention.

Finally, I would like to refer to two statements which the Food & Drug Administration made in the Federal Register. One, on May 27, 1975, the second on September 3, 1975, which both say substantially the same thing, and I am quoting from the May 1, it says, "In the opinion of the Commissioner, a trade association or other membership organizations has standing to sue in the court to represent its membership in such matters, and the Food & Drug Administration will not impose procedurally objections to such standing.

Thank you.

THE COURT: Yes, Mr. McMorrow?

MR. MC MORROW: Good morning, your Honor. We object to the intervention at the last minute of the National Fisheries Institute for several reasons.

First, our apprehension that their intervention at this point in time will expand the scope of the trial.

THE COURT: How will it do that?

MR. MC MORROW: That remains to be seen. I am apprehensive --

THE COURT: How could you so confidently predict that?

MR. MC MORROW: Well, I can't, your Honor. But it's an apprehension on my part. The fact that their intervention in this trial will enable the defendants to, even if they are permitted to challenge the regulations and introduce live testimony, your Honor, we are apprehensive, your Honor, that it would result in their presenting witnesses to this Court or expanding the scope of the testimony in a fashion that would otherwise not be permitted where only the defendant is the party to this action.

With respect to the intervention, we note that one of the multiplicities of litigation, and yet the intervention here is not of members of the individual

smoke processors. It is an industry organization, and there is no assurance. Indeed, the actual members of the industry arguably are not bound by the determination of this Court. They are coming in through an organization which, itself, is not a smoked fish processor, and the determination of the Court will not -- it will enable this matter to be litigated again, should it come up with an action by or against another individual smoked fish processor.

THE COURT: In other words, you are saying, you mean this is not a class suit, knowing an intervention can't make it such.

MR. MC MORROW: Yes.

THE COURT: I take it everyone would agree on that?

MR. MC MORROW: If they are the NFI, and would want to be a representative of the class, that is representative of a class of smoked fish processors or if the individual smoked fish processors themselves want to intervene, then we might look at this differently, your Honor, and I note also that the NFI had an opportunity to participate, and they did in fact participate in the rule making, in that after the notice of NFI, submitted comments. They indeed have had an opportunity to be heard on the issue of the regulations.

Furthermore, as far as the FDA statement is concerned, I believe this is read in the context of declaratory judgment actions or similar actions directly challenge proposed or promulgated regulations, and not in the context of an endorsement action. In this regard, the NFI has had some five and a half weeks to commence an action to challenge the regulations and it has failed to do so. It seems if it was truly protecting the interest, we are interested in the interests of the constituent member organizations, the proper route would have been some time ago to commence an action challenging the validity of the actions; not wait until the Government has commenced an endorsement action and then, as that action is about to go to trial, to seek to intervene. For those reasons, we would oppose it.

THE COURT: Well, the case isn't mere public interest, City against the Regents, I don't think gives any point because that was a case in which consumers were challenging the validity of the regulation that purported to prohibit posting prices for prescription drugs. The adversaries, in fact, to the controversy were not so much the rule-making authority. They are as consumers as against pharmacists, and a representative of the pharmacists was allowed in, essentially

to take up the cudgels to the pharmacist, because the Board of Regents presumably, at least one would hope, would have approached litigation in a calm and dispassionate way, try to glean information from the proceeding, rather than try to knock the consumer down, to the rein, which is what pharmacists have been expected to do. The language of Rule 24(b) suggests in a way that intervention ought to be permitted unless it rules away or prejudices the adjudication of the rights of the original parties unduly.

So I think that means that I ought to ask you, Mr. Morey, what it is you plan to do, because very frankly, I think an intervenor on the basis of what little procedure we have had in the case thus far would be little more than a fifth wheel, frequently very helpful if one of the other wheels falls off. But I wonder what your being here could contribute, and what the Association's being here could contribute, other than embarrassment, which could not, from the Association's point of view, be as fully and adequately protected by your joining your efforts with Mr. Einstein's and at the conclusion of the case, filing papers amicus curiae or whatever other belief was appropriate to that occasion. I say that because

I think that would be presumptuous for me to suggest that Nova Scotia is not adequately represented, and I think you have indicated that you would work closely with the defense counsel, so I take it this is not a case in which there is some conflicts in practical or strategic views which would make the association wish to intervene, not because he thought the defense was inadequate, but because he thought he was making some strategic choice which did not suit the interest of others who might be affected of the precedential effects of the case as decided.

When I say I don't see what your intervention could do except contribute embarrassment, what I have in mind is, we have eleven, I guess, Circuit Courts of Appeals. If you intervene and the Government wants you in this Circuit, that will make the case sound as though it was an industry defeat, and not that the determination should be read, at all, almost as if it was a determination and a class suit which it certainly is not.

So I say, I am not one of the foolish men who thinks that you shouldn't get help whenever you can get help. Be glad for any light that can be brought to the case, but I am concerned that we are not of an intervention which will serve no useful purpose, not

ever served, and more safely served by assistance given to defense counsel, and independent views submitted through a brief submitted at the end of the whole case.

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MR. MOREY: I appreciate your Honor's analysis. I think it's correct. The reason that we have moved to intervene is that we wanted to indicate to the Court the strongest possible way we could, that we do regard this as basically a matter of issues involving the whole industry, not just Nova Scotia Products.

THE COURT: You see, I would not dare to decide the case on that basis, because you see, I have to decide the case in terms of whether or not this particular defendant or set of defendants have or have not conformed to a regulation, and to attempt to decide with them and Government counsel whether I have any right to, by and beyond around the regulation . I think this record makes it perfectly clear that a spokesman of the industry has indicated that he considers the regulation invalid and damaging to public interest, as well as to the interest of processes.

But, the Government's contention is that that kind of relief is fully available to you by direct challenge before the department and the F.D.A., and by appeal to the National Court, and that this parochial controversy is not the one in which to debate

the larger issues.

MR. MOREY: Your Honor, we disagree with the Government as to the form. We would like to do this, but I would say to the Court that in terms of how the case will be presented, it will be presented exactly the same whether or not intervention is granted.

THE COURT: What Mr. McMorrow wants to know is are you going to call any witnesses not called by Mr. Einstein.

MR. EINSTEIN: Your Honor, the witnesses will be exactly the same, whether or not the National Fisheries Institute intervenes.

THE COURT: Is that an unequivocal undertaking?

MR. EINSTEIN: Yes, your Honor, it is. And I would say whether or not intervention is granted, I would ask that Mr. Morey examine some of the witnesses because we haveprepared the case in our way in our preparation, but the actual witnesses and their testimony will be identical. I make that undertaking to the Court.

MR. MOREY: I join in it.

THE COURT: Well, would Mr. Morey be doing anything that he could not as definitely do, if he

were your co-adjutant to the case, without involving the association, and the risk of an adjudication binding upon the association.

MR. EINSTEIN: I think the presentation would be the same. As to the risk of the effect of an adjudication, that is something that has been carefully considered, I am told, by the Board of Directors of the National Fisheries Institute, and they had determined they wished to intervene. By a vote of that board they have considered and passed upon that question.

MR. MOREY: That's correct. We didn't move to intervene before, because it was necessary to appear before the Court, and the board wanted the case explained for them and they would decide it was in the interest of the association to seek to intervene.

THE COURT: Mr. McMorrow.

MR. McMorrow: Well, I still have two problems your Honor. First, that the contingent members of the N.F.I. Organization, that encompasses will not be bound by their court's determination, and I don't think that they decision of this case is going to be precluded by those members in the event that

the Government does prevail, from arguing in later enforcement actions that they are not bound by this Court's decision.

My second concern again, I note that they did participate in the rule-making proceeding. In fact, one of the decisions is which they are seeking to challenge the regulations in question, one of the alternative time temperature perameters was one by the industry, itself, in their comments. So, for these reasons, I just think it's inappropriate to permit the industry to intervene.

If Mr. Morey wants to be co-counsel on this case, that is his prerogative, but as far as the industry is concerned, we object to their participating as the organization, the N.F.I., in this proceeding.

MR. MOREY: Your Honor, precisely, because of the matters such as Mr. McMorrow just raised about N..F.I.'s earlier participation, that we feel that it is essential to be in this proceeding.

For example, what Mr. McMorrow says about our suggesting a time temperature perameter is true, but it can be not fully understood unless other material which we later submitted to the action, is also shown to the Court.

THE COURT: You mean your 1972 petition?

MR. MOREY: No, your Honor. I am talking about further submissions we made with respect to the G.M.P. regulations. I am not talking about the so-called Whitefish Petition at this time.

We had further meetings with the agency. The N.F.I. and another association submitted further comments which may or may not have been considered, but were certainly submitted to the action for that purpose and should have been considered. They are not in this administrative record.

Further, as our joint briefindicates, our position has been that these regulations, and the reason we didn't challenge them at the time was because we did not consider them legally binding --

THE COURT: Did not?

MR. MOREY: Did not. And we further advised our clients at that time that they could be challenged in enforcement proceedings, and our clients replied on that, even not seeking judicial review of them at thetime.

MR. MCMORROW: Your Honor, may I just make one comment on that: I am not familiar with precisely what Mr. Morey is talking about, information

submitted to the agency subsequent to the date, upon which the regulations were promulgated. Well, since these regulations aren't the regulations in controvery or in question, obviously the administrative records which support these regulations are not very well matters which were submitted subsequent to the date of the promulgation.

However, if information, scientific information and technical information disproving our undercutting the regulations was subsequently submitted to the agency, then that should have been subject to a petition for reconsideration, and that petition for a reconsideration should have been the subject of a separate proceeding.

MR. MOREY: May I correct one statement in fact.

I am talking about other documents between the proposal and the promulgation, finally offered, which are not in the administrative records. That is precisely what I referred to.

There is also a subsequent one which we do contend.

THE COURT: You mean it's not included in the administrative record, which in all its modest

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proportion seems to have been presented by the Government here?

MR. MOREY: With all that, your Honor, they left out several things which we consider very significant.

THE COURT: That may be, because that is an imperfect return to the proceedings to the extent that this is a proceeding or an attempted proceeding to review the rule. But that is another matter.

Now, I think the motion to intervene will be granted with great doubt and hesitation, and on the understanding that it will not delay or procedurally expand or prejudice the adjudication of the rights of either the Government or Noval Scotia, David Sklar.

I must, however, insist that counsel be perfectly clear that it will be held to the representation underlying the grant of admission, because I think very great weight must be attached to what Mr. McMorrow has said, that this adjudication could not bind a single member of the association.

So that in a way, the heart of the association standing is all but stopped by that consideration. What you have advanced is that the association may

have an interest of individual disembarrassment to protect. Since it may be in a position of wanting to try them before the Court, the advice is rendered to its clients or to its membership of that right to challenge the validity of the regulation and inforcement proceeding.

Since that issue has already been raised by the defendants, Nova Scotia, Sklar and Sklar, that issue will not be expanded and the association, if it turns out to be right, will at least be able to say, "See, I told you," to its membership. If it turns out to be wrong, they can at least say, "We thought we were right, and enough of our position to spend time and efforts attempting to make it good" with the cooperation of Nova Scotia and Sklars.

Do you want any momentary recess while you talk about things? As for myself, for another purpose, I want to get something started in chambers.

MR. McMORROW: Thank you, your Honor.

MR. EINSTEIN: Your Honor, I would suggest --

THE COURT: Just a minute.

MR. EINSTEIN: Your Honor, I would suggest that both Mr. McMorrow and the other side of the courtroom have filed briefs and rather than submit --

make opening statements I would suggest to your Honor that it might be helpful as guidance in our presentation and on rulings as we go along, if you had an opportunity to review those. So I do welcome --

THE COURT: I am not sure Mr. McMorrow has had an opportunity to review them.

MR. MCMORROW: I haven't, your Honor.

MR. EINSTEIN: He did serve me, so you can hand it up now.

(Whereupon Mr. McMorrow handed the documents up to the Court.)

THE COURT: I don't like to read things until I am sure the other side has got them in hand. However, your's will be docketed and filed.

MR. MCMORROW: Yes, your Honor.

MR. EINSTEIN: That has been served on Mr. McMorrow, your Honor.

THE COURT: Yes.

MR. EINSTEIN: He just brought it directly into chambers this morning.

THE COURT: Okay.

MR. MCMORROW: And your Honor, we have a reply to the counterclaim, the intervener, the National

Fisheries Institute, which we would like to file.

THE COURT: A pleading?

MR. MCMORROW: A pleading, your Honor. A plea to the counterclaims contained in there as therein, parallels our response to the defendants.

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MR. EINSTEIN: I think before recess the final thing I ought to point out to your Honor is that Mr. McMorrow and I have consulted and agreed to waive Rule 615 of the Rules of Evidence which deals with the exclusion of witnesses; so that all witnesses may be present throughout the trial.

I have trouble with these new numbers, myself.

THE COURT: I was surprised to see it in there. I didn't know how it got in. Was it mandatory?

MR. EINSTEIN: No. It is a request of a party, but I just wanted to inform your Honor of that.

THE COURT: Neither of you is making a request?

MR. MCMORROW: No, your Honor.

THE COURT: Because I had always thought of that as one of the things that was very emphatically discretionary, because there were some cases in which it's quite important that one witness hear another if time is to be saved.

For example, in a battle of experts, it is so important for experts to hear another, and not read about it in the wee hours of the morning from the transcript.

(Whereupon a recess was taken at 9:50 o'clock a.m. until 10:15 a.m.)

THE COURT: I can't honestly say I committed this to memory, this brief, but I think I understand enough for us to move forward.

MR. EINSTEIN: Your Honor, I just want to point out this is Mr. David Sklar, who is seated at counsel table with us. He is president of Nova Scotia.

THE COURT: In his capacity as client?

MR. EINSTEIN: Yes, your Honor.

THE COURT: I take it he doesn't also happen to be a lawyer?

MR. EINSTEIN: No, he is not.

THE COURT: I don't want to give you the impression, Mr. Sklar, that people happen to be lawyers. They achieve that status.

MR. MCMORROW: Shall we proceed, your Honor?

THECOURT: Yes.

MR. MCMORROW: By way of opening comments, very briefly, the Government's case is really quite simple.

In chief, we will establish that the defendants, Nova Scotia Foods, its principals, David and Emanuel Sklar, did violate what we will refer to as the good manufacturing processes.

The regulations set forth in 28 CFR 128A,

sub-part 1, for the processing of hot smoked fish. We propose to call as our first witness, the F.D.A. investigator who on two separate occasions in July of 1975 and February of this year, conducted an examination and inspection of the hot smoked fish processing plant owned by the defendant, and will establish that they are in violations of the applicable regulations.

We believe that the violation of the regulations alone entitles us to the injunctive relief sought.

As our first witness, we would like to call Diana Kolaitis.

D I A N A J. K O L A I T I S, having first been duly sworn by the Clerk of the Court, was examined and testified as follows:

THE CLERK: State your name, please.

THE WITNESS: Diana J. Kolaitis, K-o-l-a-i-t-i-s.

THE COURT: Middle initial again was?

THE WITNESS: J.

THE CLERK: Thank you.

Please be seated.

DIRECT EXAMINATION

BY MR. MCMORROW:

MR. MCMORROW: Your Honor, before starting our examination of Miss Kolaitis, we would like to offer to the Court the Federal Register, a photocopy of the pertinent pages of the Federal Register in which the proposal, the notice of proposed rule making with respect to the G.M.P.'s was published as well as the pertinent pages of the Federal Register.

We ask that the proposal be marked Plaintiff's exhibit 1.

THE CLERK: Marked plaintiff's exhibit 1 for identification.

(So marked.)

MR. MCMORROW: And we ask that it be offered now into evidence and ask that this Court take judicial notice.

MR. EINSTEIN: No objection.

THE CLERK: Now plaintiff's exhibit 1 in evidence.

(So marked.)

THE COURT: Received.

MR. MCMORROW: We ask that the photocopy, a duplicate of the regulation as promulgated be marked plaintiff's exhibit number 2.

THE CLERK: So marked.

MR. EINSTEIN: No objection.

MR. MCMORROW: And we offer this in evidence.

THE CLERK: Now plaintiff's exhibit 2 in evidence.

(So marked.)

DIRECT EXAMINATION

BY MR. MCMORROW:

Q Would you please state your name --

THE COURT: Just a minute, please.

Let me take a look at these.

(pause)

All right.

Q Would you please state your full name?

A Diana J. Kolaitis.

Q Bywhom are you employed?

A I am employed by the Food and Drug Administration.

Q How long have you been employed by the Food and Drug Administration?

A I have been employed for three and ahalf years.

Q In what capacity are you employed?

A As a Food and Drug investigator.

Q How long have you been employed as an investigator?

A For the same period of time, three and a half years.

Q Would you please tell us your educational background?

A I graduated from Brooklyn College in 1971 with a Bachelor of Science degree, and a minor in chemistry.

Q What additional training have you received since you have been employed by the F.D.A.?

A In May of 1974 I attended the National Canners' Association Better Process School. In October of 1974 I attended the F.D.A. sponsored Hazard Analysis and Control Boards, critical and control points inspection.

Q Would you briefly describe your duties as an F.D.A. investigator?

A As an investigator I conduct establishment inspections of Food and Drug and cosmetic plants. I also collect samples and make other investigations.

Q And your examinations are not restricted to any one type of plant?

A No. They are in all commodity areas.

Q Have you ever conducted examinations of hot smoked fish processing plants before?

A Yes, I have.

Q How many such examinations have you conducted?

A I have conducted five inspections.

Q Is that including the two inspections of Nova

Scotia Food Products?

A Yes.

Q In your capacity as an F.D.A. investigator, have you ever had occasion to inspect Nova Scotia Food Products?

A Yes, I have.

Q Could you state the times -- the date on which these inspections were conducted?

A On July 8th through the 11th, 1975, and February 23rd to the 26th, 1976.

Q What was the purpose of these inspections?

A The purpose of the inspections was to determine the firm's compliance regarding the good manufacturing practices for smoked fish products.

Q Now, did you have guidelines which you followed in your inspection?

A Yes.

In addition to the good manufacturing practices regulations, we have inspector's guidelines which are found in the inspector's guidelines manual.

MR. MCMORROW: I ask that this photocopy of three pages of the Inspection Operations Manual be marked plaintiff's exhibit 3.

THE CLERK: So marked. Marked plaintiff's

exhibit 3 for identification.

Q Now, Miss Kolaitis, I show you a photocopy of three pages from the Inspector's Operations Manual.

Are those the guidelines which you are referring to?

(Documents handed to witness.)

A Yes, they are.

Q And would you explain how this manual related to the G.M.P.'s or the good manufacturing practices?

A The guidelines follow the G.M.P.'s and set up practice points for the inspectors to follow in conducting an inspection. They give us some guidelines as to what to look for in the G.M.P.'s, and of certain precautions for the inspectors to take, and certain points to concentrate on while doing the inspection.

Q Did you follow these guidelines in the conduct of your investigations of Nova Scotia Food Products?

A Yes, I did.

MR. MCMORROW: I ask that plaintiff's number 3 be offered into evidence.

MR. EINSTEIN: We have no objection.

THE COURT: Received.

THE CLERK: Now plaintiff's exhibit 3 in evidence.

(So marked.)

Q Would you explain how you began --

THE COURT: Just a minute.

How do you offer it if you don't let me look at it?

MR. MCMORROW: I have an extra copy, your Honor.

Q Will you explain --

THE COURT: Just a minute.

I haven't seen it yet.

Q How did you begin each inspection of Nova Scotia Food Products?

(continued on next page)

DIRECT EXAMINATION

BY MR. MCMORROW CONTINUING:

A Upon entering the firm, we would present our F.D.A. to the person of the firm, and issue a notice of inspection.

Q Did your inspections require you to follow the processing of the fish throughout the various stages of the plant?

A Yes, they did.

Q Are you therefore familiar with the layout of the plant?

A Yes, I am.

Q To help the Court understand the nature of your inspection, and those things which you look for in the course of your inspection, could you briefly describe to us, using this diagram, the layout of the plant, where the various processing stages, processing stages of the processing occur, and what it is you look for at that stage of the processing.

Starting at the very beginning.

MR. MCMORROW: I would ask that this diagram be marked as plaintiff's exhibit 4.

THE COURT: Have you gentlemen seen it?

MR. EINSTEIN: Only this morning. My client advised me that it appears to be generally accurate.

There may be some question about some of the proportions.

THE COURT: Is measured accuracy claimed for?

MR. MCMORROW: No, your Honor. It is really for the purpose of clarifying the presentation.

THE COURT: Not to scale?

MR. MCMORROW: It doesn't. Not to scale; simply to the nature of the inspection.

THE COURT: If you find something wrong with it, it can be brought out.

THE CLERK: So marked as plaintiff's exhibit 4.

MR. MCMORROW: We offer it into evidence. Do you have any objection?

MR. EINSTEIN: Subject --

THE COURT: Subject to what's been said.

THE CLERK: So marked as plaintiff's exhibit 4 in evidence.

Q So, would you please explain, using this diagram, where the processing begins?

THE COURT: You don't have any pictures of that yet; have you?

MR. MCMORROW: No, I don't, your Honor. It

paper.

Q Using this pointer, could you take us through the various processing stages using this diagram?

(Whereupon the witness stepped down from the witness stand.)

A The firm is divided into two levels.

This would be the lower level (indicating), and this would be the upstairs level (indicating). They are connected by a ramp at this point (indicating). The upper level is about two to three feet higher than the lower level.

This courtyard area is used for the receipt of raw fish products that are going to be processed by the firm. Any wet work involving any of these fish products would take place in the wet work area, and in process materials may be stored in refrigerators. Usually, it's refrigerator number 10, although it may be others in this area (indicating).

The upstairs level is also the location of the firm's six brick ovens and the firm's one electronic oven. This is also the area where the salt metering machine is located, and the firm's supply of salt.

The offices of the firm are located on the lower level, and in this area (indicating) we have two temperature control cooling rooms, one and two. In addition, we have refrigerators 3 and 4 which are used to store finished

products in refrigerated state.

This area is also the location of the refrigerators for finished products and two freezers for the same purpose. And basically, that would be the setup.

Q Okay.

Will you explain what the first stage in the processing of the fish is that you conducted?

A The fish would be received in the wet work area, and that would be the initial processing. It would be the thawing of the raw fish, rinsing if they are iced.

Q How are the fish received?

A The fish are received either in frozen state or received in crates with ice in them.

Q Do they have to be cleaned?

A The fish are usually dressed, they are viscerized. They do undergo additional visceration processes and scaling by the firm.

Q What do you look for in this stage?

A We look to see if the fish are going to be thawed. This is depending on how the firm, on the continuous motor overflow in this firm in the continuous motor overflow, this firm does not exceed 45 degrees temperature.

We also look to see after the fish are cleaned and placed in a brine solution, we monitor the temperature

during that.

THE COURT: Who does that?

THE WITNESS: The inspectors would do that.

THE COURT: But the firm always places them in a brine solution. What do you say? During the inspection you monitor the temperature at which the brine solution is held?

THE WITNESS: Yes.

Q What is it that you look for in your inspection during the brine process?

A Well, during the inspection, we would take an initial temperature reading of the prepared brine solution before thewhite fish are placed in that solution, and also we would take an additional salinometer reading of that solution.

THE COURT: Salt meter?

THE WITNESS: Right.

Q Could you explain what the salt meter actually measures?

A Okay.

The salinometer is basically a thermometer set up in degress measuring the concentration of salt per gallon of brine, and this will be read in degrees and will be reported at the beginning of the brine operation, and also at the

conclusion of the brine operation.

Q Where do you take these salinometer readings?

A According to the guidelines, we take the salt which may have been picked up by the fish during the brining operation.

Q How long are the fish actually soaked in the brining solution?

A During our inspection we noted that this varied with the Whitefish.

We monitored from the complete overnight period.

Q What happened?

A During the first inspection, the inspector soaked in brine solutions overnight, because the fish had been received in a fresh condition or on ice, and this would require longer brining periods. During our second inspection, the fish was received frozen, and the brining period varied during this inspection depending on how much salt the firm felt they wanted the final product to have.

Q What happens to the fish after they are brined?

A After the fish are brined, they are in the refrigerator. After the refrigerator, the conclusion of the brining operation, they are brought to the wet works area. The brine would be drained, and they would be rinsed for a length of time which varies from ten to thirty minutes,

and then the White fish would be transferred to a hanging tank, a stainless steel hanging tank, at which time it would be hung on the stainless steel smoke sticks.

Q Would you explain what a smoke stick is?

A A stainless steel smoke stick is approximately 36 inches long, maybe more, and has prongs running the length of the stick on either side, which are inserted through the tails of the fish so the fish are hanging upside down on each side of the stick. The Whitefish are hung on the sticks.

Q Would you explain how they are hung?

A They are removed from the water by employees of the firm --

THE COURT: Is this a hand operation?

THE WITNESS: This is a manual operation; right. And they are placed on the sticks, the tail portion of the fish are stuck into the prongs.

In addition to the Whitefish, the stainless steel support hooks are used to hold the fish in the smoke sticks.

Q What happens after the fish are hung on the smoke sticks?

A This would depend on whether the fish had been in the brick or electric ovens. Then, the fish are placed on the overhead oven racks which run on a rail system through

the fish, and are placed into the refrigerator to await processing by the smoker and the smoker's assistant. If they are going to be processed in the electronic oven, they are brought directly over to that area and placed in that oven.

THE COURT: What is that? A microwave oven?

THE WITNESS: No. This is a gas oven.

THE COURT: It's just electronically controlled?

THE WITNESS: Right.

Q Could you explain the basic other differences apart from electronic controls between the electronic oven and the so-called brick oven?

A The brick ovens run from floor to ceiling and they have a set of gas jets running the length of the oven on either side. There are no other controls in that oven; as opposed to the electronic oven, it is a four stair oven with an internal control panel which allows the operator to register any amount of smoke and heat that he wishes to apply to that oven. It is a hot air circulation.

Q Does it provide for humidity control as well?

A Yes, it does.

Q How is that done?

A We didn't witness that being done during our inspection, and I couldn't say how that is done.

Q Then am I to understand that the inspection process after the hanging on the smoke sticks is a drying process?

A Yes.

Q Would you explain how this happens?

A When the smoke assistant comes in in the afternoon, the wet work has been cleaned, and no wet work is going on in that area. The two oven racks of Whitefish are removed in the refrigerator and brought to the wet work area.

They would be placed over charcoal pots and fans in that area, and are allowed to dry, depending on temperature conditions, and also weather conditions. The length of drying would vary with that.

Q If the fish cooled in the electronic oven, then they would not be dryed in the charccalpots.

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A Immediately after hanging the fishes brought over to the electronic oven, and drying would take place in the electronic oven, itself.

Q Would you please explain and describe the drying, cooking and smoking operation which takes place in the ovens?

A In the brick ovens?

Q Yes.

A In the brick ovens the fish are placed into the brick oven after undergoing a drying period in the wetwork area, under a low gas flame, and it's additionally placed on charcoal pots that are necessary or that the smoker feels that the fish are dried sufficiently, he will rotate the front oven rack so the fish that are exposed to the greater heat are put in the back of the oven, and he will start the cooking procedure. This will be done at higher temperatures, higher gas temperatures and also additional charcoal pots in the oven. And once that is completed, the smoking operation will begin.

Q How is the smoke created?

A It is created. The gas jets would be turned off and the smoker assistant would place two piles of excelsior and wood shavings into the oven, wet it down and light it. It would be placed in for approximately 45 minutes or until

such time as the smoker felt what the firm what it to be.

Q Could you roughly describe how long the entire drying process from drying through smoking takes? Approximately how long each process takes in the brick ovens?

A In the brick ovens on the day of our inspection, it would be removed sometime around in the afternoon, around six o'clock, and dried in the wetwork area, and it would vary from one to two hours. They would then be placed in the oven for additional drying for possibly for another hour, and then for another hour cooking, and approximately 45 minutes of smoking.

Q Now, during the cooking and smoking process, do you record the temperature of samples of the batch of fish that is being cooked and smoked?

A Yes, we do.

Q How do you do this? What kind of instrument would you use?

A We use a pyrometer.

Q What does that do?

A That would give us -- that allows us to probe certain fish within the brick oven, within the oven, and monitor the temperature throughout the cooking and smoking operation.

Q Now, I show you this particular item of equipment.

Is this what you mean by the pyrometer?

A Yes, it is.

MR. MC MORROW: For the purposes of identification, I ask that this be marked.

THE CLERK: Now Plaintiff's Exhibit 5 for Identification.

Q To help us understand how you actually measure the temperature of the fish, could you explain how this machine operates?

A The pyrometer is equipped with approximately nine plugs and those are plain. They are -- I guess, fish-hooked shaped, and attached to the pyrometer with a cord, cable.

THE COURT: They don't have a barb on them, they just curl?

THE WITNESS: Yes. It's a formed hook.

THE COURT: Sharp-pointed hook?

THE WITNESS: It's relatively sharp, yes.

Q What part of the fish do you insert it?

A Loin muscle of the fish. I think it's called the biggest muscle of the fish. For each probe, we get an individual reading by adjusting one of the probes and are able to read on the meter the temperature on the probe at any given time.

Q Can you also monitor the temperature of the oven itself?

A Yes. One of the probes that we use would be left as an ambient, a probe. In other words, it would not be in any of the fish.

Q In other words, just hanging?

A Yes.

Q What did you do with the samples which you have probed?

A They would be collected, and in addition to any other fish that was required for the sample, and they would be submitted for analysis.

Q What kind of analysis was conducted on those fish?

A White fish, they would be checked for salt content.

Q Do you have some sort of method of insuring that the fish you have probed are the ones which are going to be submitted to the salt analysis?

A We try to identify -- when we place the probes in the oven, we monitor the fish. When the fish came out of the oven, during the February inspection, we used a toothpick so we could identify them after the cooling process.

Q Could you please explain what the cooling process

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is, that is the process that takes place after the cooling and smoking?

A Yes, it is. Once the fish are removed from the oven they are brought to one of the cooling areas, number one, and allowed to cool until they are packed.

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Q Now, could you please tell us what it is that you -- going back one moment to the smoking, the cooking and the smoking operation: What is it that you inspect for or look for at that stage of the processing?

A We look to see what temperatures the oven reaches while the fish are being cooked and smoked.

Q And what is it that you inspect for at the cooling stage of the processing?

A The fish are cooked to 50 degrees within the time requirements in the GMP's, within the three hours, and we would also check after 12 hours in cooking, to see if they have reached 38 degrees.

Q What takes place after the cooling process?

A The fish are packed into lined cardboard boxes and placed into the refrigerator.

Q Now, does that stage of the processing take place in your presence?

A We witnesses the packing of one of the lots of fish during the February inspection. As a matter of fact,

packing operations took place while we were not at the firm, usually between three and six in the morning.

Q Now, do you make any inspections subsequent to the packing operation or subsequent to the cooling period?

A Yes, we do. We would try and be present at the firm within the 12 hours after the cooling operation to check the temperature of the fish.

Q What do you check for at that moment?

A 38 degrees.

Q Is that required by the GMP?

A Yes, it is.

MR. MC MORROW: You can be seated again; thank you.

(Whereupon, the witness returned to the witness stand.)

Q Let's turn to the most recent inspection that you discussed, conducting of Nova Scotia Food Products, which I believe was in February of this year. What dates did this inspection occur?

A It started on 2/23/1976 and went until 2/26/76.

Q What did you do first?

A On entering the firm, we presented our credentials and issued a notice of inspection to Mr. Emmanuel Sklar.

Q What transpired next?

A At that point we discussed with him the first production schedule for the week, so we could determine what products we would follow and monitor for that inspection.

Q What product did you determine to monitor?

A We determined to monitor three batches of whitefish and one batch of chubs.

Q Now, with respect to the batches of whitefish, how did you identify them?

A The firm assigns a batch number to every batch of fish that they process. We would incorporate that number in our records and we followed the fish in that manner. We followed batch 5497..

Q With respect to 5497, at what process did you pick up the monitoring of that batch?

A That batch was in a brine solution when we arrived at the firm on the 23rd. It had been placed in that brine solution from 2/20, the previous week.

Q Now, did you monitor that batch while it was being cooked and smoked?

A Yes, we did.

Q Did you take pyrometer readings on that batch when it was being cooked?

A Yes.

Q What kind of oven was this?

A It was cooked in one of the firm's brick ovens. That would be brick oven No. 4.

Q And what stage of the process did you actually insert the pyrometer?

A We inserted the probes as the two ovens of whitefish were being placed into the brick oven.

Q That was after the drying?

A The before the additional drying in the brick oven.

Q How long did the actual cooking and smoking take?

A The actual cooking after the drying period took from approximately three and a half hours --

THE COURT: You mean after the drying period in the furnace?

THE WITNESS: In the oven, yes.

Q How many fish did you probe?

A We probed six fish, and we had one ambient probe.

Q Where was the probed fish located in the oven?

A We had a probe in the area rack. We had one probe in the back of that rack, one in the middle, and one in the front, and we had the same --

Q The ambient probe was where?

A It was attached to the front of the back oven rack and it was allowed to read the temperature between the racks.

Q Now, will you please tell us what is the highest temperature which is reached by each probed fish, and how long was it maintained?

MR. EINSTEIN: As recorded on her pyrometer, obviously.

THE COURT: Just a minute. You must have that. All right.

Q Before you answer that question, could you explain to us, did you have occasion to have this pyrometer calibrated to insure its accuracy before you conducted your February inspection?

A Yes. It was calibrated on February the 20th, Friday, before the inspection, at the New York district laboratory.

Q And you, personally, delivered the machine?

A Yes. We personally brought it back to the laboratory that was going to do the calibration.

Q And it was returned to you by the laboratory?

A No. We picked it up by the laboratory after the calibration on Friday afternoon.

Q Now, would you please tell us what was the highest temperature as indicated by your pyrometer reached by each probed fish, and for how long was this temperature maintained?

A We had high temperatures of 131, and that was the highest temperature of that probe at the end of the smoking operation. 131 for 15 minutes; 176 was the highest temperature for probe No. 3. 153, that would maintain for ten minutes; 136 for 10 minutes and 160 for 10 minutes.

Q Now, were there fans or other devices in the oven which would circulate the heat?

A No. Not in the oven itself.

Q Now, were the readings you made in compliance with the GMP?

A No, they were not.

Q Did you have any -- did anyone tell you -- did you have any knowledge what temperature the processor was attempting to achieve at that time?

A No.

THE COURT: I am sorry.

MR. EINSTEIN: I was just inquiring whether she was attempting to talk about a conversation she had, but she answered, "No," so it's irrelevant.

Q So you didn't know whether or not they were

trying to reach 150 degrees for 30 minutes or 180 degrees for 30 minutes.

A No. Not at that time for that batch, no.

Q Now, was there an indication or recording thermometer on the oven so the smoker could tell what the temperature was?

A No.

Q Is there any way for the smoker to tell in the oven?

A The only way is to remove the indicating thermometer and check with the indicating thermometer in the oven or to place one in the oven.

Q Was there any way for him to tell what the temperature of the particular fish in the oven was, without removing the fish, to the best of your knowledge?

A Not at this time, no.

Q What inspections did you conduct after the smoking was finished?

A For batch 5497 we watched it being removed from the oven and being placed into the cooler. We monitored the batch until it reached 50 degrees and then we subsequently returned the next day and witnessed the packing of this batch.

Q Incidentally, what time did the cooking operation

take place? Was it completed that evening?

A The cooking operation -- if the fish was removed from the oven on 10:30 p.m. on the 23rd, and 50 degrees at 12:10 a.m.

Q And you then left the plant?

A Yes.

Q Did you come back the next morning?

A We returned approximately 7:30 the next day, and the fish were being packed in the cooler, and we took a temperature.

Q And did you find that they had reached the prescribed temperature?

A They were still below 50 degrees, and so we checked at 10:25 a.m., and we noted that the fish had reached 38 degrees.

MR. EINSTEIN: Excuse me, your Honor. She said that she returned at 7:30. Is that a.m.?

THE WITNESS: Yes.

Q So with respect to batch 5497, the violations of the GMP's which you noted was the failure of any of the fish to comply with the time temperature requirements, and the absence of a time temperature recording device on the oven.

MR. EINSTEIN: I object to using conclusions

as to what his --

THE COURT: What did you mean by the report as violations?

MR. MC MORROW: Yes, your Honor. What she did report and what she naturally observed.

THE COURT: I think the point that Mr. Einstein states is what she discovered and treated as a violation, but the question as to whether it was or wasn't is for the Court and counsel to determine. Is that what your point is?

MR. EINSTEIN: Yes, your Honor.

Q So, in your record, in your observations --

THE COURT: By the way, just to make it absolutely clear, all the temperatures have been Fahrenheit?

THE WITNESS: Yes, your Honor.

Q You indicated in your records what you thought were two violations of the GMP, namely the failure of any of the fish to comply with the time temperature requirements, and, secondly, the absence of the point sensitive recording temperature recording device or indicating thermometer on the oven.

A Yes. That is what we reported to the firm.

Q 5614, which I understand is the second batch of whitefish that you monitored --

A Yes.

Q What stages of the process did you commence monitoring?

A On our arrival to the firm, that batch was in a thawing tank, and it had been placed there from the previous day, the 22nd --

THE COURT: What was the batch number?

THE WITNESS: 5614.

THE COURT: That was in a storage tank?

THE WITNESS: It was in a thawing tank. It was defrosted.

THE COURT: What was that?

THE WITNESS: That would take place in the wetwork area under a continuous water overflow.

Q And you followed that batch through the brining process?

A Yes, we did.

Q Now, in which oven was this particular batch of fish cooked?

A That was processed in the electronic oven.

Q That means that the drying took place in the electronic oven, also?

A Yes, it did.

Q And did you monitor the heating of the samples

of batch 5614 with your pyrometer?

A Yes.

Q How many fish did you probe?

A We probed six fish, and also had one ambient probe.

(Continued on next page.)

Q Would you please tell us what were the highest readings your pyrometer indicated for each fish, and how long this temperature was maintained?

A We had 124 at the conclusion of the processing in the oven; 152; 154 was maintained for ten minutes; 161 was maintained for ten minutes; 147 for ten minutes, and 163 for ten minutes.

Q Now, did the electronic oven have an indicating thermometer and recording device?

A Yes, it does.

Q Did you compare the results of your reading with the oven thermometer?

A Yes. We noted the method for operating at the same time we noted the first controls also.

Q Was there any discrepancy between the two?

A We noted that the highest temperature for this batch was 155, so it was within the range of our readings.

Q Does the electronic oven probe just one fish?

A Yes. Just one.

Q What observations did you make after the fish had been taken out of the electronic oven?

A They were placed in the cooling room and again we monitored until the white fish reached 50 degrees within a 12 hour period. We returned to the firm the next day at 7:30,

and the fish were packed during the night, and they were stored in refrigerator number three, and we found it to be 38 degrees.

Q With respect to 5614 you observed and recorded what you believed to be a violation of the GMP, in that the fish did not reach the prescribed time temperature requirements, they were not cooked for the prescribed time?

A Yes.

Q Let's move to bath 5602; is that correct?

A Yes.

Q At what stage of the processing did you commence monitoring this batch?

A We monitored the batch from the placement of the raw fish into the sawing tanks; from the sawing operation and until the cooking and smoking operation.

Q In which oven was this batch placed?

A 5602?

Q Yes.

A This batch was processed in the electronic oven.

Q Did you again monitor the heating of samples of 5602 with your pyrometer?

A Yes.

Q How many fish did you probe?

A We probed six fish and one ambient probe.

Q What was the highest temperature reached by each probed fish, and how long was this temperature maintained?

A We had 145 for 15 minutes, 142 for 15 minutes, 146 for 15 minutes, 151 for 15 minutes, 144 for 15 minutes, and 150 for 15 minutes.

Q Did you know -- had you been told what temperature the smoker was trying to achieve in the oven?

A Yes. During the processing the smoker was trying to maintain 150 for 30 minutes.

Q Why was that?

A Because --

MR. EINSTEIN: Objection, your Honor.

THE COURT: Did he state to you why?

THE WITNESS: He told us that he believed that the batch had been brined to contain five per cent salt.

Q Now, after the completion of the cooking and smoking, did you monitor the cooling of the batch to see that it reached 50 degrees?

A Yes, we did.

Q Did you take any further temperature readings of this batch?

A On the 26th, the following day at 9:30 when the fish was in the refrigerator -- that would have been refrigerator

number four, and we found the white fish arranged in temperature from 40 to 44 degrees.

Q What time did they come out of the oven?

A They came out of the oven at approximately 2:05 the previous day.

THE COURT: P.M.?

THE WITNESS: P.M.

Q And you took your reading at what time the next morning?

A 9:30 a.m.

Q What were you looking for?

A We were looking to see if the fish had maintained a temperature of 38 degrees.

Q Within what time period?

A After 12 hours of the cooking. The 12 hours after the cooking would have been at 2:05 a.m. on the morning of the 25th, at which time the plant was closed.

Q And that's an observation you made pursuant to your manual instructions?

A Yes.

Q What was the range of the readings?

A They ranged from 40 to 44 degrees.

Q Was any explanation given to you or any statements made to you explaining why the temperature was not at 38 degrees?

A Well, the explanation given to us for the temperatures above 38, was that fish once placed into the cooler remain there until the packer comes in at 3:00 a.m. At that time the temperature in the cooling room would be raised to about 50 degrees, and at times we were told 60 degrees so that the employees could pack the fish, and then it was placed in the refrigerator. So at that time, they were undergoing an elevation of temperature.

Q If the fish -- could you explain to me within 12 hours after removal from the oven, can they then be cooled to 38 degrees, and in your opinion or based on your observations in compliance with the GMP's --

MR. EINSTEIN: Objection.

THE COURT: Did you interpret the GMP as --

MR. EINSTEIN: Objection.

THE COURT: Did you interpret the GMP as a requirement for the fish to reach the 38 degrees before packing or could they reach it after packing if they reached it within 12 hours. Is that the question?

MR. MC MORROW: Almost.

THE COURT: Then get it exactly right.

Q In one previous examination of the batch, your reading had indicated that the fish had been packed and had reached 38 degrees within 12 hours of the time they came out

of the cooler?

A Yes. We found that in 5497 and 5614.

Q In this particular instance they had been packed before your reading, but in the morning twelve hours had expired or transpired from the time that they came out of the oven until the time you took the reading?

A Yes.

Q Yet they had not reached 38 degrees?

A Yes.

MR. EINSTEIN: Objection, your Honor. I don't see how she can testify they hadn't reached 38 degrees. She wasn't there.

THE COURT: Had not been maintained; is that right?

THE WITNESS: Yes.

THE COURT: That's your point.

MR. EINSTEIN: Yes.

Q But in any event, at 9:30 when you took the reading, the readings were from 40 to 44 degrees?

A Yes.

Q Did a representative of the company take readings at that time also?

A Yes. Mr. David Sklar also took readings at that time with us.

Q Did you observe the readings that he took?

A Yes. They agreed with the readings we found.

Q With respect to batch 5602, you noted what you indicated in your records and what you believed to be two violations of the GMP's, one, a failure to comply wich the time temperature requirements for cooking, and a failure to cool the product to 38 degrees or maintain a temperature within 12 hours of the cooking.

Now, did you point out each of these violations which you indicated in your records to be a violation of the GMP's which you observed in the course of your inspection to Mr. Sklar?

A We did. At the conclusion we presented Mr. Sklar with a list of inspectional observations, and at that time we reported our findings to him.

Q Incidentally, in the course of your monitoring various stages of the processing, did you also observe the equipment in the plant to see if it was in compliance with what you perceived to be compliance or believed to be compliance with the GMP's?

A Yes, we did.

Q What other deviations, what you believed to be deviations, did you note?

A We observed that raw fish was being stored in

refrigerator number ten, the end process refrigerator, and this was noted on the 26th --

THE COURT: Wait a minute. Can I have that back again?

(Whereupon the last answer was read.)

MR. EINSTEIN: Excuse me, your Honor. May I have a word with Mr. McMorrow?

(Whereupon an off the record conversation was held.)

MR. MC MORROW: Your Honor, we are going to pursue the point of the separate storage areas. So I ask the Court to disregard that last comment. We will move on to other observations.

Q Miss Kolaitis, apart from the fact that they were not in separate storage areas, what else did you observe?

A In addition, we noted that certain freezers and certain refrigerators lacked temperature control devices in the refrigerators, freezer number 8, 6 and 5, and refrigerators number 9, number 3 and number 7 lacked a recording thermometer.

(Continued next page)

Q Now, with respect to the brick ovens, did you, other than those in which the batches were cooked, did you notice any other of what you perceived to be violations of the GMP?

A None of the six brick ovens in the firm have a temperature recording device.

Q Nor do they have indicating thermometers?

A No, they do not.

Q Apart from what Mr. Sklar's response when you discussed these observations with him, apart from the first one about the separate storage areas, what was said?

A In regard to the temperature equipment on the freezers, on the refrigerators in question, Mr. Sklar stated that most of these refrigerators, with the exception of No. 3, were scheduled to be replaced during the planned renovations of the firm, and that he couldn't see any point in installing the temperature equipment if they were to be so replaced.

Q What other observations did you discuss with him?

A We also discussed the fact that the brick ovens did not have a temperature recording or indicating devices, and he stated that if the electronic oven was to work out -- in other words, was to meet the firm's standards for quality product, then they would be -- the brick ovens would be

replaced with the other electronic ovens, and again he did not want to install any temperature equipment if they were going to be replaced.

Q Did you discuss the time temperature requirements?

A Yes, sir, we did.

Q What was his reaction to your observations?

A Mr. Sklar --

MR. EINSTEIN: Objection. Can we get a response rather than a reaction.

Q It was his response to your observation?

A Mr. Sklar stated that his opinion, the fish could not be processed at 180 degrees for 30 minutes and still yield a commercial, acceptable product.

Q Did you discuss the electronic oven?

A Yes. He felt that the firm was getting better results with it, and discovered with it in an attempt to produce a product that was commercially acceptable.

Q Let us now turn to the July 1975 inspection. Now, on what dates was this inspection conducted?

A On July 8th through the 11th, 1975.

Q And what time did you arrive at the plant on the first day?

A We arrived at the plant at approximately eight o'clock, 7:30 a.m.

Q What did you do then?

A We presented our credentials and we issued a notice of inspection to Mr. David Sklar.

Q Did you then get a production schedule from him?

A We discussed with him what wish were going to be produced during that week, and we decided what batches of whitefish we would monitor.

Q Which batches did you decide to monitor?

A We would monitor batch 4398 and batch 4406.

Q These were the batch numbers --

THE COURT: Both whitefish?

THE WITNESS: Yes. Both whitefish.

Q What stage of production was batch 4398 in?

A 4398 was in a brine solution in the refrigerator when we arrived at the firm on July 8th, and it had been placed in that brine solution since the previous day.

Q How did you know that?

A That was stated to us by Mr. Sklar.

Q Now, did you take any measurement or reading at that time?

A We took a temperature of the whitefish and temperature of the brine, and also took a salinometry of that brine solution.

Q What did your temperature readings indicate?

A The temperature on July 8, the whitefish ranged in temperature from 44 to 46 degrees, and the brine temperature was 40 to 44 degrees.

Q What did you conduct this measurement -- for what are you looking for in that?

A We want to determine if the brine and whitefish are being maintained at 38 degrees.

Q In your opinion, it's your understanding that the GMP's require that the fish be maintained in the brine at 38 degrees?

A Yes, continuously lower within 12 hours, to 38 degrees.

Q Now, in what kind of an oven was batch 4398 cooked?

A One of the firm's brick ovens.

Q Did you take pyrometer readings on samples of this batch?

A Yes.

Q How many fish did you probe?

A Eight fish and one ambient.

Q What was the highest temperature reached by each probed fish, and how long did it maintain that temperature?

A The temperature was of 153, 164, 162, 151, 171,

176, 154 and 161, for five minutes.

Q Those were all for five minutes?

A Yes.

Q Now, what observations did you make after the fish had been removed from the oven?

A We monitored the fish after they were placed into the cooler, and we noted that they did reach the prescribed 50 degrees within three hours.

THE COURT: They were reduced to what?

THE WITNESS: They did reach the 50 degrees. We monitored them to see if they reached 50 degrees within three hours.

Q What time did you leave the plant then?

A We left at approximately 11:15.

THE COURT: P.M.?

THE WITNESS: P.M.

Q What time did you take them out of the oven?

A They came out of the oven at 9:45, 9:50.

THE COURT: P.M.?

THE WITNESS: P.M.

Q Now, did you return the next morning?

A Yes, at 9:50. We reported the temperature at 9:50 the next day.

Q Using an indicating thermometer?

A Yes.

Q What did your readings indicate?

A Fish ranged from 44 to 48 degrees.

Q That was 12 hours after they had come out of the oven?

A Yes.

Q Was Mr. Sklar or anybody with you when these readings were taken?

A Yes, they were. Yes, he was.

Q Did he make any statement to you concerning why the temperature was between 44 and 48 degrees?

A Again, the explanation given was that during the packing operation, the temperature in the cooling room is elevated to about 50 or 60 degrees for the comfort of the employees, and that it was lowered after that was finished and the products are placed in the refrigerator.

Q So, with respect to batch 4398, you observed what you believed to be three violations of the GMP's; the failure to brine at 38 degrees or below; the failure to cook and smoke the fish at the prescribed time temperature parameters; and the failure to reach and maintain temperature of 38 degrees within 12 hours after cooking?

MR. EINSTEIN: I --

THE COURT: I think counsel is about to object.

I suggest it might be in regard to the question as a leading question.

MR. EINSTEIN: Thank you, your Honor.

Q Let's move to batch 4406. Is that the final batch you monitored?

A Yes, it is.

Q And what stage of processing did you --

THE COURT: Now, this one we just looked at then was 4398; right?

THE WITNESS: Yes, it was.

Q Now, at what stage of the processing did you commence your monitoring of batch 4406?

A We began monitoring that batch when it was removed from the refrigerator, as it had been received and placed into a stainless steel tank for rinsing.

THE COURT: Pleaced in what?

THE WITNESS: A stainless steel tank.

Q And you followed this through the brining process?

A Yes, we did.

Q Did you take any measurement at the brining stage?

A Yes. We took initial temperature salinometer readings and also during the brine operation.

Q What did the temperature reading during the

brine operation indicate?

A It indicated that -- the next day we took a reading at 9:45, and that was 22 hours after the whitefish was in the frozen brine batch. We noted the temperature of the whitefish to be 44 degrees and the brine to be 41 --

THE COURT: And the brine?

THE WITNESS: 41 degrees.

Q That was a double brine?

A Yes. This batch was double brined. It was placed into a second brine solution for an additional overnight period.

Q So you took two readings; one for the first brining?

A Right.

Q And one for the second?

A Right.

Q Now, did Mr. Sklar make any statement to you concerning the reasons why these temperatures were reached?

A At the conclusion of the inspection again, when we presented our observations to Mr. Sklar, he was surprised that the fish did not reach 38 degrees, and at that time we suggested that he have the refrigerator unit checked and possibly consider that too many products were being stored in that unit.

THE COURT: Was the 40 degrees within --

THE WITNESS: It was two degrees above the requirements.

THE COURT: I know. But is the requirement an absolute 38 degree requirement or has a tolerance?

THE WITNESS: I know of no tolerance.

(Continued on next page.)

Q In what kind of oven was this batch cooked?

A It was cooked in a brick oven.

Q Did you take pyrometer readings of sample fish in this batch?

A Yes.

Q How many fish did you probe?

A We probed eight fish and one ambient.

Q Could you please tell us what was the highest temperature that your parameter indicated each probed fish reached, and how long did it maintain that?

A We had 163, 162, 151, 161, we had a temperature of 182 for five minutes, and another temperature of 180 in that same fish for an additional five minutes, 147 and 162.

Q Is there one probe reading missing?

A Yes. During this monitoring, we had the fish that was monitored with probe number three fall off the hook, and the probe was reading an ambient temperature after that.

Q At what stage?

A That would have been at around 8:20, and that would have been the beginning of the cooking operation.

Q Do you know what the temperature was when the fish fell off?

A Yes. It was at 104 degrees, at 8:10 o'clock.

Q T hese readings would appear to be on the average

somewhat higher than the others. Was this explanation stated to you by Sklar for this?

A Yes. When we discussed the observations again at the conclusion, Mr. Sklar said that he noted that the readings were quite high, and indicated that the batch had been cooked in an oven that had been used that same night to cook another product just prior to this ambient temperature, and external temperatures were higher.

Q Did you monitor this fish after it came out of the oven?

A Yes, we did.

Q What were your readings?

A We monitored to see if the fish would reach 50 degrees within three hours, and they did so, and we returned the next day and checked the fish that had been packed during the night and in the refrigerator, and we found that the temperature ranged from 36 to 43 degrees.

Q How many fish did you check?

A Thirteen fish, and the thirteen were above 38 degrees.

Q Did you measure these with an indicating thermometer?

A Yes.

Q What time was that?

A That was at eleven a.m., the following day, on July 11th.

Q What time did the fish come out of the oven?

A They came out of the oven at 11:05 p.m.

Q Now, at the end of the July, 1975 inspection, did you have occasion to discuss your observations with Mr. David Sklar?

A Yes. We presented Mr. Sklar with the list of observations.

Q Now, you have already noted what Mr. Sklar's reaction to the brining, what you perceived to be a deviation from the GMP with respect to the temperature during the brining -- no, excuse me. Would you kindly tell me what his observations were with respect to what his response was when he stated to you in response to your observation with respect to the deviation that you perceived from the brining requirements?

A There was no explanation given. Mr. Sklar said they did not have a problem with that in the past, but he did agree to have the unit checked.

Q Did you discuss with him the time-temperature requirements?

A Yes. He was surprised that 4406 had reached such a high temperature, and he told us they were not

manufactured or processed any differently for our benefit, and that he had instituted the double-brining procedure that we noted during this inspection in an attempt to reach a salt concentration of 3.5 and above.

He also added that he felt that he could not reach 180 for thirty minutes, as required, and still yield a commercially acceptable product.

Q Did you discuss with him the failure which you perceived to be the failure of the fish to reach and maintain 38 degrees after twelve hours of cooking?

A Yes.

Q What was his response?

A He gave us the explanation that the cooler temperature was raised during the packing operation, and that the fish was placed into the oven after that, and stated they would remain there until reaching 38 degrees, and would not leave the plant until they did so.

Q Now, while you were conducting your examination in July of 1975, did you have occasion to note any other what you regarded as deviations from the GMP's apart from eliminating any refrigerators to separate storage facilities?

A Yes. We noted again that the refrigerated units and freezer units did not have proper temperature control, in that refrigerators No. 7 and 3, and freezers No. 6 and 8, did not have a recording thermometer, and freezer No. 5

and refrigerator No. 9 did not have an indicating or a recording thermometer.

Q Did you discuss this with Mr. Sklar?

A Yes, we did.

Q What was his response?

A He again -- at that time he told us that the firm was planning to have renovations done, and that certain of these refrigerators and freezers would be eliminated during that renovation.

Q Did you notice any of what you regarded as deviations with respect to the brick ovens?

A Yes. The brick ovens did not have a temperature recording device to monitor external ambient temperatures.

Q Was any explanation stated by Mr. Sklar for that?

A Only that if the electronic oven which had recently been installed in the firm had worked out, these brick ovens would be replaced.

Q Miss Kolaitis, contemporaneous with your examination and investigation of the defendant's plant, did you take notes which you incorporated into this inspection report?

A Yes, I did.

MR. McMORROW: I ask that these two reports

be marked. This is the February, 1976 report.

THE CLERK: Plaintiff's Exhibit 6 for identification.

(So marked.)

MR. McMORROW: And the July, '75 report.

THE CLERK: Plaintiff's Exhibit 7 for identification.

(So marked.)

THE COURT: Which is the later report?

THE CLERK: Plaintiff's Exhibit 7, your Honor, July, '75.

MR. McMORROW: The later report, your Honor, is Plaintiff's Exhibit 6.

Q I show you these reports (handing). Are these memoranda which you prepared on the basis of the notes that you took during your inspection?

A Yes, they are.

Q Now, were you assisted in the conduct of this inspection?

A Yes. On the 23rd to 26th, I was assisted by Investigator Edward Morocco.

Q Does his name appear at the end of this report also?

A Yes, it does.

Q Did you both observe -- did you both personally make the observations which are recorded in the report?

A Yes. We both made the observations.

Q Did you both participate in the preparation of this report?

A Yes.

Q It is your normal business to prepare such reports?

A Yes. We do this routinely with FDA.

Q Are these reports maintained by your agency?

A Yes.

MR. McMORROW: Your Honor, at this time I would ask that these reports be introduced into evidence.

MR. MOREY: May we see them?

THE COURT: Are these copies of the reports?

MR. EINSTEIN: I would like to see specifically what he is offering.

(Whereupon the documents were handed to Mr. Einstein.)

MR. McMORROW: We now offer these into evidence.

MR. EINSTEIN: No objection, your Honor.

THE COURT: Received.

THE CLERK: Yes, sir, as Plaintiff's Exhibits 6 and 7 in evidence.

(Plaintiff's Exhibits 6 and 7 for identification now received in evidence.)

Q Now, Miss Kolaitis, --

THE COURT: Just a minute. I want to make sure of what this is. All right.

Q Miss Kolaitis, at the conclusion of your monitoring of the cooking and smoking of samples in each batch of whitefish, did you then collect samples for further analysis?

A Yes, we did.

Q What was the purpose of this?

A For the purpose, so that the fish could be analyzed for salt contents --

THE COURT: For?

THE WITNESS: Salt contents.

Q Now, how did you go about collecting samples?

A We would wait until the whitefish -- we monitored each to the temperature of 50 degrees. We would try and collect the fish we had probed during the cooking and smoking operation, and any additional fish which were required during the sampling we needed. This is usually ten whitefish.

Q And what did you do with the fish after you had collected it? What did you do with the samples?

A After we collected, we would take the fish, place

them usually in a plastic bag, which is identified with the sample usually with our initials, and what the product is, and the number. We would put it in a cardboard box and place an FDA official seal on that sample, and during these inspections we would place the sample in the firm's freezer and they were picked up either the last day of the inspection or in the second inspection. They were picked up on the Wednesday and Thursday of the inspection.

Q Could you give an identifying number to the samples which you took during the February, 1976 inspection?

#10

A Yes, we did. Batch No. 5497 was collected, and initials FDA, sample 7641506.

Q What was that batch number?

A 5497.

MR. EINSTEIN: Your Honor, Mr. McMorrow is laying a foundation to show that the fish was transported to FDA Laboratories, and then inspected and tested. We are not contesting that. T here is no need for him to lay this tortuous chain to link the fish to the laboratory.

THE COURT: All right. Take any thought you might want to know about time and temperature during transfers and the few other things --

MR. EINSTEIN: Unfortunately the FDA isn't

required to comply with their own regulations.

MR. McMORROW: Your Honor, we have entered into a stipulation of facts which I am going to introduce into evidence in a moment where the parties have agreed to --

THE COURT: What?

MR. McMORROW: The stipulation provides that the parties would agree that were the FDA chemist called to the stand, he would testify that the results of his examination are as they are set forth in the stipulation, and in the exhibits which are attached.

THE COURT: Which are his reports?

MR. McMORROW: Yes. His work sheets. But I don't believe that what I am doing is that tortuous, and it's important to tie in each batch to the temperature it was cooked at with the subsequent salt analysis of this batch. It's important that the two go together.

MR. EINSTEIN: We admit each numbered batch is.

THE COURT: I think we are talking about will they tie in with the hooked fish, if I can call them that. That is the tale of the stipulation?

MR. EINSTEIN: Yes. I am sorry. I didn't mean to interrupt Mr. McMorrow and delay the proceedings. I thought I was trying to speed them along. I will sit quietly if Mr. McMorrow wants to continue.

MR. McMORROW: All I was doing then --

THE COURT: Go ahead and do it.

BY MR. McMORROW:

Q Just briefly go through it. Could you tell us which sample number is related to the sample number 508, which batch was that related to?

A Batch 5614.

Q And sample No. 509?

A That was batch --

THE COURT: 506 is 5497?

THE WITNESS: Yes.

THE COURT: Then what?

THE WITNESS: 508 is 5614, and 509 is 5602.

THE COURT: Is the one marked?

MR. McMORROW: I believe there are two more samples, 201. I believe, your Honor, that I was just trying to tie in the samples with the batch number. I believe that the stipulation is not less tortuous than the testimony, your Honor, but I believe that the stipulation will tie in the specific batch numbers

with the respective sample numbers, one must simply go through and correspond the two. I ask that this be marked as Plaintiff's exhibit next.

THE CLERK: Plaintiff's Exhibit 8. Marked Plaintiff's Exhibit 8 for identification.

(So marked.)

MR. McMORROW: And now we offer it into evidence.

MR. EINSTEIN: I signed it. I guess I can't object to it now.

THE CLERK: So marked as Plaintiff's Exhibit 8 into evidence.

(Plaintiff's Exhibit 8 now received into evidence.)

MR. McMORROW: I have no further questions. Thank you.

THE COURT: Let's have a short recess so I can find out what is in the stipulation.

MR. EINSTEIN: Your Honor, she has been referring to a rather substantial sheet of notes on the witness table. I would like a chance to inspect these during the recess.

THE COURT: Fine, sure.

(Whereupon a recess was taken at 11:40 A.M. until 11:50 A.M.)

CROSS-EXAMINATION

BY MR. EINSTEIN:

Q Miss Kolaitis, when you made these reports that have been introduced into evidence, they were based upon some notes thatyou took?

A Yes.

Q Did you preserve those notes or have they been thrown out?

A No. They are destroyed when we prepare the reports.

Q Now, you mentioned that you had conducted five processing inspections: two of Nova Scotia and three of other places?

A Yes.

Q What other plants?

A Blue Ribbon Smoked Fish Company, Montrose Smoked Fish Company and Marshall Smoked Food Products.

Q And do you recall when those inspections were, approximately?

A Approximately between the period of 1972 through 1974.

Q And in these inspections, did you monitor hot smoked whitefish?

A Yes, we did.

Q Did you check the time-temperature requirements in those three inspections?

A Yes, we did.

Q And did you find whether any of those companies, in your opinion, were in compliance with the GMP?

MR. McMORROW: Your Honor, I object to this line of questioning on the basis of its relevancy.

THE COURT: Overruled. I think it is irrelevant, but I know the point counsel is going to make. As long as it doesn't take too long we will let him have it.

A No. As far as I recall, they were not.

Q That is as to the time-temperature requirement?

A Yes.

Q Thank you. Now, in your inspection at Nova Scotia in July of 1975, did you find any evidence of dirt or rodents or filth or anything of that nature?

A No, we did not.

Q How about in the February, 1976 inspection; did you find evidence of dirt or rodents or filth or things of that nature?

A No, we did not.

Q Now, did you receive any information or instructions from FDA as to the reasons for the time-temperature

requirements contained in the good manufacturing practices?

A No.

Q Did anybody ever tell you that they were designed to deal with the specific biological hazards called botulism?

A Yes. T hey may have been mentioned during my time at FDA.

Q Were any of the fish that you collected at Nova Scotia analyzed for the botulism, spores, or toxin?

A As far as I know, they were not.

Q So you have no knowledge one way or the other as to whether botulism, spores or toxins were present on any of the Nova Scotia whitefish?

A No, I do not.

Q Now, the testimony that you have given here as to your inspections relate solely to whitefish; is that correct?

A Yes. Both the February and July inspection covered whitefish. The February inspection also covered the monitoring of chubs.

Q That is not involved here?

A No.

Q Now, in this pyrometer that has been marked as Exhibit 5 for identification, does that create a chart

of the various readings as it is in operation?

A This particular unit has a recorder, but we haven't used it.

Q So that to make the readings that you have testified to, you must, I assume, turn the dial to each of the probes, look down and write it down on a piece of paper somewhere?

A Yes.

Q Do you do that alone or does somebody check your readings?

A Well, we will do that at the same time. In other words, one inspector may read the probe, the other will write it down. It would just depend on the inspector.

Q And you're monitoring nine probes every five minutes; is that correct?

A No. It would vary. The number of probes and the number may vary, also.

Q At Nova Scotia, how many probes were you monitoring?

A During the first inspection of July, we had nine probes that we monitored, and during the inspection of February, there were seven probes.

Q And your recordings on your charts are every five minutes?

A In some cases, every five minutes. In some cases, maybe greater time intervals.

Q How long does it take you at any point in time, say at 6:10, to run these number of probes?

A I would have no way of knowing; possibly one minute.

Q It's done rather rapidly?

A Yes.

Q Now, you say that this pyrometer was calibrated. What do you mean by that?

A Well, we would turn it over to the laboratory and check. They would check to see whether each probe was reading accurately.

Q Did you observe what the Laboratory did in checking the probes?

A No.

Q You were not there at the time?

A No.

Q And do you know whether anybody verifies each probe as against a standard instrument which is known to be accurate?

A I am not familiar with the calibration procecure.

Q YOu just know you put this in a laboratory

and something came back to you?

A Right. And we received a memo of that calibration.

Q Now, you have referred to the brick ovens that the firm has. Do you know whether they are referred to in the business as gravity ovens?

A No. I haven't heard that term.

Q If I use the term, please take it to refer to the term --

MR. EINSTEIN: I think, your Honor, the trade refers to them as gravity ovens.

THE COURT: Why?

MR. EINSTEIN: I don't know why. That is the term that is used.

Q With respect to these ovens, can you describe what they look like?

A The brick ovens?

Q Yes.

A Well, they run -- the height is from the floor to the ceiling, approximately, and they are brick, all brick walls with a set of gas jets running along the bottom.

Q It is kind of like a big --

A Overhead rail system to accommodate the oven racks.

Q And the fish go on the racks and are placed into the oven; is that correct?

A Yes.

Q Now, during the cooking process, the oven doors are kept open or closed?

A It would vary. They may be closed, but not completely. They may be ajar at certain times.

Q Isn't it true that when open air gets in there to allow the flames to burn?

A I don't know why. We know that the doors were kept open.

Q W hen you take your pyrometer probes and you run them into the fish in the oven, you are running them through that open space in the door?

A No. It's running them through a porthole on one of the oven doors.

Q On the fish -- placed on the fish them?

A Yes.

Q When the fishes are rotated, as you have testified, the rack is pulled out of the oven and turned around; is that correct?

A Yes, in front of the rack.

(Continued on next page.)

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BY MR. EINSTEIN:

Q And this is done in order to assure a more even distribution of the heat, because the oven temperature is not uniform in this kind of an oven; is that correct?

A Yes.

Q Now, during the time that that rack is pulled out of the oven, is some adjustment made in the degree of flame that comes out of those gas jets on the bottom?

A The degree of flame is increased when the rack is put back in or a pot may be added.

Q During a cooking process, is the rack rotated?

A We were told it was, at the end of drying and cooking, to begin immediately after that.

Q Is the rack rotated during the cooking process, to your knowledge?

A No. We did not see that.

Q Did you observe the entire cooking process?

A No.

Q You didn't see that?

A No. It was only rotated once.

Q Were the probes in the fish at the time that the rack was rotated?

A Yes.

Q Did that rotation require removal or doing

something with the probes?

A No. We determined before we inserted the probes or start the actual monitoring, whether the firm is going to rotate the racks or not, and this would situate the probes in such a way, and the lead requires that we would allow the situation of the rack, and not have any of the probes fall out.

Q But during this time that the rack is out of the oven for rotation, do you have to adjust the probe in any way?

A Just making sure there is enough slack on the probe wires so it won't be pulled out.

Q Do any of the probes on occasion fall out?

A I haven't had that happen.

Q Didn't you note a few probes falling out on some of your reports there?

A Not during the rotation. The smoker went into the place and he pulled on the cable wire, and caused the probe to fall.

Q Have you had occasion to note on other inspections that the probes fall out?

A No.

Q Never seen that?

A No.

Q Now, you stated that the brick ovens didn't have a thermometer; is that correct?

A Yes.

Q And I think you also said there was no way you could know the temperature; is that correct?

A We said there were no dials on the oven that you could tell the temperature, other than if the smoker used an indicating thermometer. That is what I said.

Q Are you familiar with the smoker who was at Nova Scotia? Have you met the gentleman?

A Yes.

Q And do you know how long he has been smoking fish?

A Quite a number of years from what I understand.

Q Based on his experience he could be familiar with the temperature in the oven?

A I don't know that.

MR. MC MORROW: Objection, your Honor. There is no basis for the testimony at this point.

Q Do you know if Nova Scotia, in fact, ever had thermometers and probes on their brick or gravity ovens?

A Yes, they did. At one time of recording thermometers this was determined by me by previous inspection reports.

Q Do you know what happened with those thermometers?

A They were removed.

Q Do you know why they were removed?

A Mr. Sklar told me FDA had conducted an inspection and found the recording thermometers were not recording properly, and so he discontinued their use.

Q Do you know of any efforts made by Mr. Sklar to get those probes working properly?

A I believe he mentioned that he tried to have them repaired, but that was unsuccessful.

Q Now, you also testified as to measuring the temperature of some of the fish in the cold storage room after packing. Do you recall that?

A Yes.

Q What kind of thermometer did you use to measure that temperature?

A We used a regular dial thermometer.

Q And do you have a sample of that here with you?

A No, I do not.

Q And it just has a point that you stick into the fish?

A Yes. It has an indentation with the sensitive point of the thermometer and that has to be in the part of the fish we want to measure.

Q And then it just had a dial on it?

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A Yes.

Q How often are these dial thermometers checked for accuracy?

A To my knowledge, they are not.

Q So you have no knowledge as to whether the dial thermometers that you used to check the temperature twelve hours or more after cooking was accurate or not?

A No.

Q Now, with respect to Batch 5602, I believe you said you had a temperature range of between 40 and 44 degrees?

A Yes.

Q Now, do you recall that Mr. Sklar put his own thermometer in and got a reading of 39 degrees?

A No. I don't recall that.

Q Did you make any notes about what reading Mr. Sklar got when he probed those fish at the same time you did?

A No. I did not make a report of that reading.

Q What did you base your testimony on that Mr. Sklar's reading was the same as the reason you got?

A Just from the notes I have. During the notes we took during those inspections.

Q You don't have those notes of Mr. Sklar's reading?

A No.

Q Do you know whether there is an allowable tolerance of plus or minus 2 degrees for all of these indicating thermometers?

A That would be the accuracy plus or minus degrees, yes.

Q So if a thermometer said 40, that would be 38 or 42?

A Yes.

Q When you get a reading of 40 about fish in 5802, and that 38 degrees with the allowable tolerances --

A It's never been my experience to use that tolerance in FDA.

Q There is --

A Only if you are referring to the refrigerator controls on the unit.

Q How about in the probe thermometers? Isn't there an allowable tolerance on them?

A The only tolerance stated in GMP's that the temperature is plus or minus 2 degrees accuracy.

Q Isn't a probe thermometer a kind of thermometer recording device?

A Yes, it is.

Q Thank you. Now, after you observed on your

readings in Batch 5602 that there was a temperature range on your thermometer between 40 and 44 degrees, did you have occasion to check that batch at a later time?

A No. That was the last day of our inspection, so it was not checked later on.

Q Now, on Batch -- turning to the inspection of July 1975, in Batch 4406, you said that you got a reading of between 36 and 43 degrees; is that correct?

A Yes. That's correct.

Q Now, what time was it that the fish came out of the oven?

A According to the time temperature chart, I have that the smoking ended at 10:50, and 11:05 the racks were removed from the oven.

Q 11:05 they came out of the oven?

A Yes.

Q What time was it that you took those readings in July, on Batch 4406?

A At 11:00 a.m.

Q So you were a little bit short of the twelve hours in that?

A The cooking operation ended at 10:50, and thats the twelve hour period we are using.

Q When it came out of the oven?

A The regulations say from the end of the cooking operation.

Q How do you determine whether the oven was turned off or when the fish comes out of the oven?

A We have been using the time gas jets extinguished from when the cooking or smoke piles, and the doors are opened, of course.

Q In Nova Scotia's case, the smoke piles follows the cooking?

A Yes.

Q And the smoke is extinguished and the doors are opened?

A Yes.

Q The fish are still exposed to smoke; are they not?

A Just what's remaining from the extinguished smoke piles.

Q The smoke is still rising to the fish?

A Not rising out to the fish. I believe the exhaust fans would be on at that time.

Q Now, you mentioned about indicating thermometers.

MR. EINSTEIN: I would ask Mr. Reporter that you mark as Defendant's Exhibit 1 a letter dated August 5, 1975.

THE COURT: Exhibit A.

THE CLERK: So marked, your Honor, Defendant's Exhibit A for identification.

(So marked.)

Q I show you what has been marked as Defendant's Exhibit A for identification, and ask you if you have ever seen this letter before (handing to witness)?

A No. I don't recall having seen it.

MR. MC MORROW: May I have an opportunity to look at it.

MR. EINSTEIN: Sure.

(Handing to Mr. McMorrow.)

Q Have you ever discussed the contents of this letter with anyone at the Food & Drug Administration?

A No, I have not.

Q Do you know whether it is contained in the files of the Food & Drug Administration?

A IT may be. I assume it is.

Q But you have never seen it?

A Not to my knowledge, no.

Q Now, what kind of thermometer do you use to record the brine temperature?

A Again the dial thermometer.

THE COURT: A what?

THE WITNESS: A dial thermometer.

Q When was the last time -- is that the same time thermometer that you use in the fish or a different one?

A It would be the same dial thermometer.

Q And you just stick it into the tank full of fish and brine?

A We would try to get a reading before the fish were placed into the brine.

Q And then, would you attempt to also get a reading of the water during the brining process?

A Yes.

Q With that same thermometer?

A Yes.

Q Would you also attempt to get a reading of the fish during the brine process with that same thermometer?

A Yes.

Q That is the same thermometer, to your knowledge, which has never been checked for accuracy?

A Yes.

MR. EINSTEIN: I have no further questions.

(Continued next page.)

REDIRECT EXAMINATION

BY MR. MC MORROW:

Q Miss Kolaitis, I show you Plaintiff's Exhibit No. 6 in evidence. Is that the memorandum which you referred to with respect to the calibration of the pyrometer, the one which appears here (handing to witness)?

A Yes, it is.

Q And that is a memorandum which you received with a pyrometer after it had been calibrated?

A Yes. We had the pyrometer before we had the memo, but we did subsequently receive the memo.

Q Thank you. With respect to the statements that Mr. Sklar made to you about his attempt to have the pyrometers which he had installed on the brick or gravity ovens, did he tell you exactly how he attempted to have these pyrometers repaired?

A I believe he just mentioned that he had the people who purchased them come in to look at them. We didn't get into details.

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Q You stated you had no knowledge of whether or not the dial thermometer had been calibrated prior to the time you used them?

A Yes.

Q They could have been calibrated that day?

A The styles are not calibrated. They are usually assigned to the inspectors.

Q It's your own?

A Yes.

Q One you used on previous inspections?

A Yes.

Q Nobody else had an opportunity to use it?

A Yes. It may be used by other people in the office.

Q If you let them use it?

A Yes.

Q With respect to 5602, you stated that your reading was from 40 to 44 degrees; is that correct?

A Yes.

Q So a number of readings which you took that time, even given a two degree or per cent for variation would have been in excess of 40 degrees; is that correct?

A Yes.

MR. MC MORROW: That is all, your Honor. I have

no further questions.

MR. EINSTEIN: No further questions, your Honor.

THE COURT: You may step down.

(Whereupon the witness was excused.)

MR. MC MORROW: Your Honor, the Government is not proposed to offer any other witnesses. We believe we have established by the testimony of the investigator a prima facie violation of the good manufacturing processes. We refer this Court to the preamble which appears in the Federal Register where the Commissioner finds that the processing requirements of the proposed regulations are the safety known as out sea botulism, Type E, and since the public health is at stake, and the smoked fish is not restricted to a single smoker, the conditions of the current good manufacturing process of this industry should be established without further delay.

We refer this Court to one of the introductory portions of the GMP, where the Commissioner stated that the criteria shall apply in determining whether the facilities, methods, practices and controls used for the manufacturer, processing, packing or holding of fish and seafood products, shall in conformance with and operated and administered to conform with good manufacturing practices, to produce food for

consumption. We would respectfully refer this case to the body of the case originally cited in our memorandum, that considering the propriety of an injunction, that violating the law of the United States, the rule is where an injunction is authorized by the State, as it is in the case, it is enough if the conditions were satisfied.

We respectfully submit that the violations of the GMP which have the force and effect of law, and about to promulgated to a rule making authority of the Commissioner, have set up criteria. They are, in fact, a particularization of statuatory requirements, and that a violation of the statute entitles, alone entitles the United States to the injunctive relief sought here, where the Government seeks by statuatory injunction to protect the health of the public and to give effect to a regulation which hazards this purpose,as this regulation clearly does.

The meanings of risk of harm for the minimization of a risk of harm to the public, that it's not necessary that the Government go any further and show that there actually has been harm.

We have established a violation of the statute which we believe, that alone entitles us to injunctive relief.

MR. EINSTEIN: Your Honor, may we respectfully move to dismiss the Government's case on the ground that they have not proved a prima facie case, and the reasons for that, I think, are set forth in detail in the trial brief which we have submitted and if your Honor would like, I can summarize them briefly.

THE COURT: Yes, if you will.

MR. EINSTEIN: Your Honor, the action is founded on a specific statute which gives the Court authority to restrain violations of Section 331 of Title 21 of the United States Code. 331 contains a litany of prohibitive acts. Nowhere in that listing will you find as a prohibitive act the violation of any regulation promulgated by the Food and Drug Administration.

Indeed, if you read the complaint in this case, it appears that the Government is seeking relief under two additional statutes; being Sections 331K which forbids the doing of any acts which causes food to be adulterated, and 332A4, which defines adulteration as being food which has been prepared, packed or held under insanitary conditions, whereby it may have been contaminated by salt, or whereby injurious to health, and I think the Government has failed to prove the doing of any acts as to this controversy.

They have not proven the contamination with,

and they have not proven any likelihood of injury to the health, so I think, therefore, the Government's case must fall.

MR. MC MORROW: Your Honor, with the consent of the Court I am going to ask my colleague from the FDA to respond to that argument.

MR. FRIEDE: My name is Arnold Friede from the Office of General Counsel of the Food and Drug Administration.

Your Honor, I think that the defendant's motion to dismiss the Government action at this point skips over several intermediate statuatory steps that have to be taken.

Under Section 301K of the Act, it is prohibited to do any act which results in the article of food being adulterated. Then, we have to turn from there to Section 342A4.

THE COURT: Just a minute now. That's right.

MR. FRIEDE: Right. The objection, removal of the whole or any part of the label or on the doing --

THE COURT: Well, the language is with doing of any act with respect to if such act is done while such article is held for sale after shipment in interstate commerce, and the results in such article being adulterated.

MR. FRIEDE: Correct. In this case we have no problem with interstate commerce. The defendants in their answer have admitted the requisite.

THE COURT: I hope so.

MR. FRIEDE: In this case we elect that the adulteration is the doing of an act, namely a violation of the regulations which results in the food becoming adulterated under Section 402A4 of the Act. The defendants have suggested that because they have no rats, vermin or filth in their plant, there was no violation of insanitary conditions, and now I would suggest that a violation of the regulations which are designed to limit microbiological contamination, that is the most elementary form of sanitation.

We seriously contend that the absence of traditional filth means they did not necessarily operate under insanitary conditions. The basic premise --

THE COURT: The word insanitary is not defined in this statute.

MR. FRIEDE: That's correct. But I would submit it refers not only to those visions we see with our eyes, but to basic biological contamination, and that if the procedure is utilized by the defendant, it is insufficient to rid their products of such contamination, then the statute is indeed satisfied.

THE COURT: These botuisms, spores and anti-toxins, are they contaminants or are they inherent when they occur?

MR. FRIEDE: They are, to my understanding, ubiquitous organisms that exist in the organisms.

THE COURT: So that what you are trying to control is something which is in the fish before it is caught and delivered to commerce?

MR. FRIEDE: That's correct. The same types.

THE COURT: So there isn't something that comes to the fish after he has become the subject of the commerce?

MR. FRIEDE: It may become part of the fish at a later time. There may be cross-contamination between the fish between them and other fish which may not.

THE COURT: They are in the hull of the ship, so to speak?

MR. FRIEDE: Or in the smoked fish establishment. Your Honor, I believe that the critical issue that is presented squarely for the Court's decision at this moment is whether or not the Food and Drug Administration has the authority under Section 701A of the Act to promulgate regulations defining more generally statuatory language, and if it does have the authority to do that, then the defendants violation of those

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regulations would be a violation of the statute, and adulteration within the meaning of the statute. The statuatory violation would be the doing of any other acts which results in the food becoming adulterated.

I submit that the Food and Drug Administration does have such sorts. In the Second Circuit -- and more specifically and precisely on the issue of whether or not FDA, under authority of Section 701 of the acts, has the power to particularize the requirement of 404. I would naturally cite the confectionery case recently decided in the District of Columbia.

THE COURT: For cocoa?

MR. FRIEDE: Confectionery products. These regulations involve the coating of the products so that in the end it was later determined there was an adulteration of which these products would be facilitated.

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MR. FRIEDE: Here we have something that is even more directly related to the recent adulteration. That is, the recent introduction of organisms in the first instance to try to kill the organism, and secondly, to try to inhibit any organisms which survive. We are attempting in this regulation to stop the adulteration in its incipiency. In the National Construction case it is contended that the D.A. had no power to particularize the section. In Section 402(a)(4) to Section 701(a) cited in the brief, it held that the D.A. had such regulations in question as to their validity and particularly the statutory language in Section 402(a)(4), and I submit in this case in the GMP regulation and particularly in Section 402(a)(4) a violation of two regulations is a violation of the statute and is therefore an act which resulted in the adulteration of food prohibited in Section 331(k).

THE COURT: Was the case you are talking about Judge Manfield's case here in the Second Circuit?

MR. FRIEDE: In the National Nutrition Food case, I believe it was the District Court, it is before Judge Frankel. You are talking about the Court of Appeals?

THE COURT: It is a Court of Appeals' decision.

MR. FRIEDE: Yes.

THE COURT: I think it came from Judge Frankel.

MR. FRIEDE: Yes.

THE COURT: I think you were talking about the same case. Did that deal with the word "insanitary"?

MR. FRIEDE: No, it did not. It dealt with whether or not the FDA had the power under Section 701 of the Act to promulgate regulations defined in the statute and prescription drugs -- there was a question whether certain high dosages of vitamins were prescription drugs.

THE COURT: We are both talking about the same --

MR. FRIEDE: The principle that it laid down, namely --

THE COURT: That's all right. But I'm just concerned with whether or not you are on totally safe ground when you say we're manifestly viewing an insanitary condition which seems to be the necessary statute to hang the rest of it on?

MR. FRIEDE: That is correct.

THE COURT: Is there any elimination of the word "insanitary" in the regulations?

MR. FRIEDE: Yes.

THE COURT: Or in the statute?

MR. FRIEDE: In the regulations, the Commissioner specifically finds -- and I read from 21 CFR, Section 128.A, subparagraph A, which Mr. McMorrow previously read.

THE COURT: Just a moment.

MR. FRIEDE: Where the criteria under 128 of this chapter shall apply in determining whether the facilities meet the practices and controls used for the manufacturing, processing, packaging or holding of fish and seafood products are in conformance with and/or operated with good manufacturing practice to produce sanitary conditions for human consumption.

THE COURT: He does not define the term.

MR. FRIEDE: T he limitation of the microbiological contamination is the insanitary condition, to which the regulations are directed and that is spelled out in the preamble to the final regulation, that is the third full paragraph.

THE COURT: You mean it's in the F R.?

MR. FRIEDE: That is correct.

THE COURT: That is not reproduced in 21?

MR. FRIEDE: No, it is not. But this is the basis and purpose that is required by the Administration Procedure Act --

THE COURT: Where is that, 35 FR?

MR. FRIEDE: Page 7401, middle column, second full paragraph in that column.

THE COURT: Commissioner finds?

MR. FRIEDE: Correct.

THE COURT: He just sort of sums it up though. He just assumes that it is correct to characterize the part in 128 (A) as a sanitation type regulation.

MR. FRIEDE: Your Honor, I believe that we have addressed the issue.

THE COURT: What?

MR. FRIEDE: I believe that we have addressed the issue of whether or not the processing condition herein involved constitutes an unsanitary condition in our preliminary and original memorandum that we filed in this action.

THE COURT: Yes, I have that here.

MR. FRIEDE: Page 23 of our original memorandum.

THE COURT: You mean sub-point 4 there?

MR. FRIEDE: That's correct. On page 23 and 24.

THE COURT: Let me read it over.

(Short pause.)

THE COURT: I see the argument.

MR. FRIEDE: We believe that the statute is to be given its meaning consistent with the Congressional intention to protect the public health from not only

visible but micrbiological contaminants.

THE COURT: In other words, you say that the meaning would be, or the application would be perfectly plain, if you were talking about gnats that got into the pudding, something of that sort. The fact that they are not visible, they are foreign matter and it does not make a difference in the least, an intrusion is made. That is what you are trying to route out.

MR. FRIEDE: That's correct.

THE COURT: Or sterilize it?

MR. FRIEDE: Well, scientifically I wouldn't say sterilize, but protect the public from.

THE COURT: Whatever it does say it doesn't say it accurately.

MR. FRIEDE: That's correct, and we suggest that the regulations were designed to implement this policy, particularize the state or requirements that the FDA has the ability to promulgate such regulations. Violation of those regulations is an adulteration under the statute and is therefore the doing of any other act prohibited by Section 301 (k) and as outlined in Diapulse and other decisions.

THE COURT: Which?

MR. FRIEDE: Diapulse and other decisions,

the showing of the statutory violation is sufficient for this injunctive relief.

THE COURT: I've had enough years in Diapulse.

MR. EINSTEIN: Your Honor, may I, if your Honor please? There has been no reported case to our knowledge where the Government has ever been granted relief, injunctive or criminal, simply because somebody violated a GMP regulation. In the only case where the issue was ever squarely raised, and it is in the Everett case, Judge Doyle was consistent and specifically held on page 11 of our brief that the Government could not seek relief simply by showing a violation of a regulation.

THE COURT: He is talking there about criminal cases, meaning reasonable doubt and all that.

MR. EINSTEIN: I think you're talking here about a civil case with the drastic remedy of an injunction.

THE COURT: You're talking about a cease-and-desist, stop doing. Because I think that when we say it is a drastic remedy, we are not talking in the context of the Government's rights here under the FCC to in effect make specific, individual and applicable mandates of the law.

MR. EINSTEIN: It is interesting, your Honor,

that the Government prosecution in the Everett case was under the same section, 331. They are proceeding civilly in this case and Judge Doyle held that --

THE COURT: As I recall 331, it is a strange and wonderful section which covers both civil relief, misdemeanor relief and felony relief, depending on how deep you got yourself in. Is that right?

MR. EINSTEIN: Yes, your Honor. But the essential element found by Judge Doyle in that case and also in the Lord Mott case, which he cited at page 12 of our brief and also --

THE COURT: That is the one differentiating part.

MR. EINSTEIN: No, Lord Mott is a District of Maryland case decided way back in 1944, where the District Court there again adopted the same views as Judge Doyle, that you cannot have a violation of a law simply by violating a regulation, that the underlying adjudicative facts have to be proven. Now, I would also point out --

THE COURT: Just a minute. Let me look at that.

MR. EINSTEIN: It is cited on page 12 of our brief, your Honor.

(Short pause.)

THE COURT: I think Judge Manfield or Judge Holt differentiates it in that case. I guess it is Judge Holt. Yes, I think 402, F.Supp. at 205, he discussed Lord Mott. Then at 206, column one, he says the Court does not agree. That is on the hearing point that we have --

MR. EINSTEIN: That is on a different point, your Honor.

THE COURT: Yes.

MR. EINSTEIN: Your Honor, I would also like to point out --

THE COURT: Just a minute. That was in the Bodine case. It was a criminal prosecution for contaminated lettuce.

MR. EINSTEIN: Lord Mott was a criminal prosecution.

THE COURT: So was Bodine. That did result in a conviction, right?

MR. EINSTEIN: Well, Bodine, I don't know. Lord Mott resulted in an acquittal, as did Everett.

Your Honor, I would like to point out a few other things. There is no evidence in the Government's case that the organism, or any microbiological organism, existed in these fish.

THE COURT: I think we're perfectly clear on

that. Nobody claims so far that any botulism has been discovered or manifested in claims back two years ago or anything else. You never had a botulism suit to fend for?

MR. EINSTEIN: Thank you, your Honor. We have not. Also, your Honor, if you read the cases on the unsanitary conditions, and we have summarized a great number of them on pages 6 and 7 of our brief, you see that they all deal with rodents in the factory, dirt, excrement, flies and insects and conditions of that kind.

THE COURT: That is what turns up in candy factories and breweries. Those two I know about.

MR. EINSTEIN: That is not at all involved here. As was admitted on the witness stand by the Government's only witness. In addition, your Honor, I am not suggesting the Government is without remedy. There is a specific provision of law, Section 404 of the Act itself, 21 USC 304, and it has a specific remedy provided: "Whenever the Secretary finds, after investigation, that the distribution into interstate commerce, in any class of food, made by reason of contamination with micro organisms, during the manufacturing process or packaging thereof in a locality, being injurious to health --

THE COURT: Could you read that to me again?

MR. EINSTEIN: It says, "Whenever the Secretary finds, after investigation, that the distribution into interstate commerce, in any class of food, made by reason of contamination with micro-organisms during the manufacturing process or packaging thereof in a locality, being injurious to health, that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then has the power to issue a series of regulations."

THE COURT: That is under 404?

MR. EINSTEIN: Yes, your Honor. What the Government is doing here is trying to squeeze out of this case and out of the GMP's a remedy which they might have under another statute. But it is clear that the present action is inappropriately based on the statute that the Government seeks to enforce.

THE COURT: Somehow or other, I don't really think you will find a welcome regulation under this section.

MR. EINSTEIN: We don't welcome this injunctive action either, your Honor.

MR. MOREY: Your Honor, in our brief, pages 9 and 10, we point out that the legislative history of Section 404(a) which goes back to the mid-1930's,

this was a provision in the original act in 1938, indicates that this provision was inserted in the Act, particularly because there had been a problem of botulism in ripe olives from California and there was a desire to have a specific provision in the statute to deal with this sort of situation, should the need arise. This 404 is specifically due to botulism.

THE COURT: Isn't that somewhat like the argument that Judge Mansfield had to deal with in the A and E debate, because was E was more specific and A couldn't apply, et cetera, et cetera, which he rejected.

MR. MOREY: Your Honor, I think it is similar, but we are of course talking about different statutory provisions.

THE COURT: Let me look back at 402.

(Short pause.)

THE COURT: They may sound cumulative and divers remedies may -- I think if you look at the whole of 402(a)(3) and not simply the language from 4, which the Government has asserted as being the point. The warrant regarding the unsanitary condition in the meaning of the statute and the meaning of the statute is plan enough. There is nothing and it seems to me incompatible in the two types of

attack.

In other words, I don't know what the history of the olives was, they come from California. I thought they all came from Greece and Italy. But I think they're talking about what happens when you've got an arrest, but the conditions which are in need of control, which apparently has gotten past the idea of and possibility of contamination of botulism into a condition of known microorganism infection, if I can call it that.

MR. EINSTEIN: Your Honor, let us deal with what the Government has brought the action on. The Government has brought a specific case. They have charged in their complaint, in paragraph 10, a violation of Section 331(k) --

THE COURT: I know.

2/2

MR. EINSTEIN: And they say that the doing of any act whereby food may become adulterated --

THE COURT: I think there is no affirmative act here.

MR. EINSTEIN: I question that quite seriously.

THE COURT: Then you are turning the heat off too soon.

MR. EINSTEIN: Then you come to Section 342(a)(4). Then they say we have done an act which makes

the food adulterated in violation of 21 USC 342. That is 404(a)(4), they rely solely on that one section. They rely on no other provision of law. There is no subdivision three but solely subdivision four. Subdivision four says, "A food shall be deemed to be adulterated if it has been --"

THE COURT: I lost my page.

MR. EINSTEIN: -- "if it has been prepared, packed or held under insanitary conditions, whereby it may become contaminated with filth, or whereby it -- whereupon, it may have been rendered injurious to health."

I say to your Honor that there is no evidence of insanitary condition. No evidence of filth. No evidence of injury to health.

Now, subdivision three, which your Honor mentioned a moment ago, I think the Government has sued on and is inapplicable here. That if the condition of filth, putrid or decomposed substances -- and there is no evidence in this case --

THE COURT: I say if you read section four, in its setting, including looking back at three and ahead to five, six and seven, I think you see you warrant four. The Government's reading of the word insanitary is in the broad way which it has.

MR. EINSTEIN: Well, the courts have held --

THE COURT: See, "filthy and decomposed substances" is in three. Then we come to something that has to do with process or condition of holding. It is quite disassociated fromfilth in one part.

MR. EINSTEIN: Well, subdivision three, your Honor, talks about the food itself being filthy or putrid or decomposed.

THE COURT: That's right.

MR. EINSTEIN: Subdivision four talks about being processed under insanitary conditions and the courts have held in Berg v. United States and a number of others, that those words should have their ordinary and usual meaning.

THE COURT: Are you both in agreement on that?

MR. EINSTEIN: I don't think it is the ordinary and usual thing to call something insanitary because a product may have, and there is no proof that it does have in this case, microbiological organisms that Mother Nature put there. That is not what the ordinary definition of insanitary condition is.

THE COURT: We have your case. Is that entirely dispositive --

MR. EINSTEIN: If the case is dispositive itself, it's Judge Doyle's decision in Everett, recognizing a

criminal case, it still makes clear the Government mustprove the elements in order to sustain its cause of action. That the Government here has not proved the insanitary conditions.

THE COURT: In other words, you would like at the beginning where he says, "No, I have to go back to the statute," is that right?

MR. EINSTEIN: That is correct. Certainly there is no proof or reasonable possibility of injury throughout. There has been no testimony on that at all.

I think we have dispose of the issue squarely to your Honor and I don't think I can add anything more until you have a specific question for me.

THE COURT: Mr. Friede is not prepared. Would you look to go after lunch or before, rather on a full stomach than --

MR. FRIEDE: I prefer to eat when it is all over.

THE COURT: You can eat while you are still in the courtroom.

MR. FRIEDE: Your Honor, first of all, with respect to the argument on the insanitary conditions: It sounds to me as if the defendants are arguing something like, if you can't see it, then we can't do anything about it. I would suggest that that is not

a proper construction of what the term "insanitary condition" means under this statute and I will leave that for a moment.

With respect, just briefly, on the issue of applicability of Section 404(a), I would suggest that that would be a potentially applicable section, but it involves emergency permit controls for temporary periods and not of a type of overall consistent regulations that we have in this case.

THE COURT: In other words, after lightning strikes?

MR. FRIEDE: WE would have the ability to go in and engage in some type of licensing operation for them for temporary periods of time. The statutory language clearly sets forth such temporary periods of time. Here, we do not have something that the regulations -- it is regulations only for a temporary period of time and we need something that is uniform and consistent with the regulations.

On the issue in the decision of the Everett case, I would just like to point out, first of all, it was a criminal case. Second, the adulteration was different than the adulteration here. And more critically, in the decision in that case, thejudge did not discuss the potential applicability of all of the Supreme Court

cases. For instances, in the Stant, Westcott & Dunning case, in 1973, U.S. v. Sebca Corporation and the Bentex Pharmaceutical, all of those cases -- nor was the National Nutritional Food case ever mentioned.

THE COURT: Some of them hadn't been decided yet. This is the most recent one, isn't it?

MR. FRIEDE: Where he went off on what seemed to be his prior -- what he said before. I don't think the issue was framed in Everett, that we had the same issue that we have here.

There was a criminal prosecution and the question was whether or not the regulations would be sufficient in and of themselves to establish a criminal violation of the Act. It is a totally different issue than we had here today.

THE COURT: I take it that is what he said in the middle of page seven of the reprint that someone gave me. That is the critical point of disagreement between you and Judge Doyle, who unfortunately for you couldn't be appealed in a criminal case. He says, early in the course of this case, "I rejected the Government's contention that if food has been prepared, packaged or held in a manner which does not meet the requirements of 21 CFR, Section 128(a)," it follows necessarily that it has been prepared,

packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

MR. FRIEDE: Then it goes on, your Honor.

THE COURT: You would say that as to that, and certainly speaking within the context of specific beliefs, by injunction, you are one hundred per cent in disagreement.

MR. FRIEDE: Correct.

THE COURT: You say you have to disagree with that?

MR. FRIEDE: Yes, I do disagree.

THE COURT: As it applies to injunctive suits. Because he in effect there has said that in the indictment or in context, the regulation is of no effect.

MR. FRIEDE: That's what he has said in that context. I disagree.

THE COURT: From that point of view and until the mere fact that it is a regulation in a criminal case, it constitutes a total ground of distinction and a valid one. You say this is squarely Mr. Einstein's authority, right?

MR. FRIEDE: And I would suggest, your Honor, specifically--

THE COURT: In other words, he is just saying it can't be adulterated within the meaning of 21 USC

Section 342, I guess that is it?

MR. FRIEDE: Not only that, your Honor.

THE COURT: Unless the Court is able to find that without looking at the regulation, which seems rather odd. What does footnote three mean?

MR. FRIEDE: I read that several times and I don't understand.

THE COURT: Did you notice that, Mr. Einstein? Footnote three on page seven?

MR. EINSTEIN: I think he means, I think he is referring to perhaps rodents or dirt or that kind of thing in the factory. He is referring to the other part of (a)(4). There are two "whereby" clauses, package, unsanitary condition, whereby it may have been contaminated with filth, or whereby it may be rendered injurious to health. When he says the Government has given up on the filth point it is just staying with the injurious to health.

MR. FRIEDE: There has been some evidence of the rodent infestation that wasn't pursued.

THE COURT: You gave up on the rats?

MR. FRIEDE: I believe that is correct. I don't believe the decision in the Everett case is dispositive on the question that we have here. That is a criminal case. This is a civil case. That was

a different charge, a different allegation in that case.

Critically, the Court in its decision never discussed the applicability of the Supreme Court's 1973 decisions on FDA rule-making authority. Those cases clearly held --

THE COURT: Which one was that, the '73 case?

MR. FRIEDE: There are four cases decided in 1973. It is Hines, Wescott & Dunning, Bentex Pharmaceutical and U.S.A. v. Pharmaceuticals -- something along those lines. There is also the Sebca Corporation versus The Secretary. Those were the four cases that were decided. They are companion cases in 1973 that established the --

THE COURT: I suppose we got used to people being ordered to jail under regulations and under the draft act where the whole ticker clause in the statute depended on your otherwise violating the law and you had to look at the regulation of the draft authority to find out what the violations was.

MR. EINSTEIN: That's not present here, your Honor. It is interesting to note, your Honor, that in the statute, the section I'm referring to is 21 USC 331, it contains a list of what is prohibited.

The very next section, 332, says you are entitled to an injunction for violating 301.

The next section, which was utilized, you cannot have a criminal prosecution for violating 301. There is a parallel construction and if Judge Doyle was right, as I think he was on the criminal end, it seems that his reasoning should carry over into the injunctive suit as well.

Your Honor, not only do I disagree with Mr. Einstein as to the parallel nature of the two sections of the statute, but I also think Judge Doyle's decision was erroneous, beyond the distinction between criminal and civil cases.

MR. MOREY: Your Honor, one other statutory provision might be --

THE COURT: Just a minute.

(Short pause.)

THE COURT: Yes, sir?

MR. MOREY: I would like to refer to Section 501. This is the adulteration provision for drugs. It is on page 35. You will note 501(a)(2) A is very similar, if not identical to 402(a)(4), and then there is (a)(2)B, which essentially provides for good manufacturing practice regulations for drugs.

There is no equivalent provision in the food

adulteration section.

MR. FRIEDE: Your Honor, I think the National Confection case is dispositive of that contention that the FDA has no authority to issue GMP regulations under Section 701 and Section 404.

MR. MOREY: I think this also bears on our position on what sanitary means.

THE COURT: As to what?

MR. MOREY: What sanitary means, your Honor, inthis suit. This authority for good manufacturing practice regulation for drugs is separated from the provision dealing with insanitary conditions, which is all you have in Section 402.

THE COURT: Didn't you have to look for another reason there? Because 501 and I don't know what the two numbers are --

MR. MOREY: Your Honor, 501 are the sections of the Act. There is a Federal Drug, Food & Cosmetic Act and 351 is the U.S.C. section.

THE COURT: Thank you. Because 351 deals with a drug or device.

MR. MOREY: Yes, a device would be --

THE COURT: A is a drug or device and B is a drug.

MR. MOREY: That's right.

THE COURT: Not a device.

MR. MOREY: Devices are in a similar position to foods. Drug is a specific provision authorizing good manufacturing practice regulations.

THE COURT: I think I would have drawn exactly the opposite inference. Since you are dealing with just foods over on 404, you don't need to break it down between drugs and devices because you have a unitary class over on 404, which is food.

MR. FRIEDE: 402.

THE COURT: 402, I'm sorry.

MR. MOREY: I think the legislative history on 501(a)(2)B, would also indicate that that was put in specifically to allow promulgation of such regulations. NOthing in similar foods, there would be nothing similar for devices as your Honor has noted.

THE COURT: Well, I am certainly not going to dismiss the case off the bench. I will tell you that. I will decline to render judgment under the Rule at this stage of the case. Here is what you have to say, without deciding the motion one way or the other, since in any case you will have to make findings of fact.

Will you please be back at a quarter past two, gentlemen?

(A luncheon recess was had.)

AFTERNOON SESSION 131

jb:em T.1/2

2:30 P.M.

MR. EINSTEIN: YOur Honor, the defendants call Melvin Eklund.

Dr. MELVIN W. EKLUND, called as a witness being duly sworn by the Clerk of the Court, testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Dr. Eklund, will you give us your residence address?

A Yes. I live in Seattle, Washington.

Q By whom are you employed?

A I am employed by the National Marine Fisheries Service, which is an agency of the Department of Commerce.

Q Other than receiving a fee for travel and expenses, are you being paid for testifying here today?

A No, I am not.

Q Will you describe to the Court your educational background?

A I have a Bachelor's degree of Science in Agriculture, in which I have had numerous courses in chemistry and in microbiology, and numerous courses in the different animal sciences. I have a Master's degree in Food Science, with strong emphasis on -- in the chemical industry and micro-

biology. And my Ph.D. degree was received from Purdue University in 1962. And there I worked very much with spoilage and food poisoning bacteria.

Q And will you tell us the work that you have done in the past years in dealing with food organisms and microbiology?

A Yes.

MR. McMORROW: Objection. I don't know what the relevancy of this testimony is. If the extent that Mr. Eklund does not intend to testify as to whether or not the defendants have in fact violated the regulations, the statute that we have alleged, then we would object to his testimony on relevancy grounds.

MR. EINSTEIN: Well, I am qualifying the man as an expert right now, your Honor.

THE COURT: That you may do.

Q You go right ahead, doctor.

A After my graduation from Purdue University, I spent my entire time as a microbiologist in charge of research at the National Marine Fisheries Service laboratory in Seattle, Washington. I spent a great deal of time with spoilage, bacteriophage, yeast and molds. And since 1963 I have been involved with clostridium botulinum.

Q Will you describe for us the work that you have been doing -- the work you have done and are currently doing with respect to clostridium botulinum?

A Yes. I started my work in 1963 in clostridium botulinum, and this was in the marine area from Alaska, all along the Pacific Coast to the Mexican border. During this process we were the first to isolate a clostridium botulinum type of nonprotein -- which does not break down proteins. And I have also -- we were the first to demonstrate that these organisms would grow and produce toxins at temperatures of 38 degrees Fahrenheit. Our additional work on that -- I have also worked with the mechanisms involved. This is basic research. Mechanisms involved in the toxic production of the bacteriophage. In other words, what factors govern the bacteria to produce its toxins.

In these studies we have isolated bacterial viruses which we found to control the toxin production of certain strains of clostridium botulinum. In this work we have been the first to show that the clostridium botulinum organism is governed by a bacterial virus.

THE COURT: What?

THE WITNESS: By a bacterial virus.

Also in this work we have done considerable amounts of work with fishery products.

Specifically, about two years ago I became very much interested in the smoked fish industry. I have continued to be in contact with the different members of the fishing industry throughout the United States because my responsibility is research of product safety, fishery product safety. And in talking with many of these processors, I realized that they were having a very difficult time meeting the GMP's.

MR. MC MORROW: I object. I don't see how this testimony refers to him as an expert.

THE COURT: I think we had better go ahead to see what the thrust of it is, and in the light of that determination, its place, if any, in the case.

Q You can continue, doctor.

A In the GMP's -- I was very much interested in the GMP's for several reasons. I am also not only interested in the quality of the product, I am also interested in the safety of the product. In our studies -- in our studies with the-- excuse me. I lost my patternof thought here.

In the studies with the GMP's, we were -- I was quite interested in this for another reason besides the micrbiological aspect. And that is, in the ham industry, for example, a process of 155 degrees Fahrenheit with 2-1/2 per cent salt, which is what is currently tolerable to the

consumer -- in other words, it's the tolerance level. If products are heated at a higher temperature, they are unacceptable. And also products with a higher salt level are unacceptable. Therefore, I saw a comparison between our work and also with what would occur in thefishery industry.

MR. McMORROW: Your Honor, I just must object because he is offering opinions as an expert without having been qualified as one.

Q Dr. Eklund, have you published any materials in connection with the work that youhave done and are currently doing, and that you have been describing to the Court?

A Yes. I have published somewhere between forty and fifty scientific articles in spoilerization, microbiology, and clostridium botulinum.

Q Have you served on any panels or bodies of that nature dealing with these areas?

A Yes. In 1966, I was invited and participated in the clostridium botulinum symposium in Moscow, Russia. And two years later I was invited and participated in the Food and Agricultural Nature of the United Nations meeting in Vienna, an expert panel on spoilerization clostridium botulinum. And several years later, it was about 1971, '72,

I was invited to participate in the symposium in England on the microbiological study on the safety of foods. And this last fall I had -- I was appointed as the Department of Commerce representative through a joint United States-Japanese Committee on Toxic Microorganisms, which includes five members from each country.

Q Dr. Eklund, you mentioned that you worked for the National Marine Fishery Service. What kind of organization is that?

A The National Marine Fishery -- the National Marine Fishery Service is an agency, as I mentioned, of the Department of Commerce. We have actually several different research areas. Some of it is involved in the technology of the fishery products. Others are involved in the surveillance as far as the occurrence of the fish in different areas. Fish and research. Fishery research, gear development, and fishery biology and a number of other areas.

Q All right. You are currently doing some work in the clostridium botulinum study?

A Yes. I am very active as are the five people with me.

Q Is that work being funded by funds provided by the National Fishery Institute Trade Organization?

A Yes. And since it is, and because of my interest

in trying to seek an alternative to the current GMP's, the industry became very much interested in this and has supported us at a level of $40,000 a year to help expedite the research.

Q That was $40,000 for this current year; is that correct?

A Yes.

Q And you're anticipating another $40,000 next year?

A That's correct.

Q Now, describe for the Court exactly what is a clostridium botulinum.

MR. MC MORROW: Your Honor, I must object. He hasn't been qualified as an expert.

THE COURT: Yes, he has.

MR. MC MORROW: Then I object to the testimony on the grounds that it is not relevant. This is not the proper forum. Unless his testimony is going to relate in some way to showing that the defendants have not violated the GMP's, I don't see how it's relevant to this proceeding. And it goes to a very crucial issue. And that's whether or not the defendants are going to be permitted to introduce scientific testimony in now challenging the regulations.

MR. EINSTEIN: Well, we intend to offer testimony through Dr. Eklund -- I won't make an offer of

proof because that would be very lengthy -- which will deal with the nature of the organism, the presence of any alleged possible injury to health based upon the processing pyrometers that are shown in the record as compared with the GMP's, and, indeed, dealing with the basis of the GMP's themselves. Dr. Eklund's testimony will deal with all three of

1P/2 those areas.

THE COURT: Well, would that be, in effect, saying that it being part of 128A of Title 21, it ought to be disregarded?

MR. EINSTEIN: Your Honor, our position is this. There are several parts to it.

First of all, as we have argued before, we claim that the Government must show a reasonable possibility of injury to health to sustain this cause of action. Dr. Eklund's testimony will deal with that area.

Secondly, we do believe --

THE COURT: Where did it say -- why do you say that? Because again, you say -- I mean, in effect, you're relying on such a decision as Judge Doyle's or what?

MR. EINSTEIN: The language of the statute --

and we are charged with a statutory violation, and in addition, your Honor, if there is no basis for finding a reasonable possibility of injury to health, then I say there is no rational basis for the regulation itself.

THE COURT: Well, then, is that not something that ought to be addressed to the Department of Commerce and not to this Court?

MR. EINSTEIN: Well, I believe under the Administrative Procedure Act we have the right in this enforcement proceeding to challenge this regulation.

THE COURT: Under what part of it?

MR. EINSTEIN: I am just turning the pages to look for the citation.

MR. MOREY: 14.

MR. EINSTEIN: What page?

MR. MOREY: 14.

MR. EINSTEIN: 14?

No, that is not it.

MR. MC MORROW: Your Honor, we don't quarrel with their right to challenge the regulations. What we are stating is that if they are going to challenge the regulation, then they are restricted to a review of the administrative record. And so --

THE COURT: That's what I mean.

MR. MC MORROW: And in so doing the Court must focus only on the administrative record.

MR. EINSTEIN: Well, the section we rely upon, your Honor, is 5 USC Section 703. That provides exceptions to the extent that prior adequate and exclusive opportunity for judicial review is provided by law.

THE COURT: What page?

MR. EINSTEIN: It's cited at page 28 of our brief, your Honor.

THE COURT: Wait a minute. Let's turn to it.

MR. EINSTEIN: It's the language that is in the quote.

THE COURT: Yes. The intent language in the footnote.

MR. EINSTEIN: Agency action subject to judicial review in civil or criminal proceedings for judicial enforcement. This is such a proceeding.

MR. MC MORROW: Your Honor, we don't quarrel with their right to challenge the regulations now. What we simply are stating is that it's clear under the applicable case law that in reviewing that decision this Court is limited to a review of the records and

it is not entitled to hear live testimony. The Court must restrict itself to a review of the materials which would be for the agency at the time that a -- that they are promulgated in the regulations.

MR. EINSTEIN: I will let Mr. Morey respond to that, your Honor.

MR. MOREY: Your Honor, I think we are getting into what we have in our point five of our brief, starting on page 14. Basically, we take the position that this large pile of materials that you have up on your desk there is not really the administrative record. This is something that was made up later and cannot be considered the administrative record because the vast majority of it -- we have had no access to it at the time they claim to have relied on it in making their decision.

And we cite in paragraph B of point five, starting on page 18, a number of cases which would indicate that we should have had that available to us if it is to be considered the administrative record for this purpose.

MR. MC MORROW: But, your Honor, that doesn't give them the opportunity to introduce live testimony. If they argue that the record is deficient, which we

believe that it is not, then the remedy is not for this Court to have a de novo hearing and to make findings of fact with respect to sophisticated scientific matters.

MR. MOREY: Well --

THE COURT: What if any cases have you got that bear out precisely what it is that you were attempting and what are you attempting? I mean what I am concerned about is a defining of the administrative remedy in this case.

MR. MOREY: We have --

THE COURT: I don't see in Exhibit 2 that there was any prospect of a hearing or any giving of a notice provided for or any invitation in any concrete form.

MR. MOREY: Your Honor, I --

THE COURT: Or in opposition to the proposed regulations. And those were things that I understood are the standard rules making procedures with which I am familiar -- which I visualize that it does not require it. Now, what kind of rule-making procedure was this and what happened?

MR. MOREY: YOur Honor, I think you should start with Exhibit 1, Plaintiff's Exhibit 1, which is the proposal. And you will see from that that this is

what I would refer to as a notice and comment rule making the -- that there is no hearing opportunity.

THE COURT: Let me remind you, one --

MR. MOREY: Your Honor --

THE COURT: Wait a minute. Where is it?

Well, the same thing applies. Now --

MR. MOREY: But our basic point --

THE COURT: Just a minute.

Yes?

Well, what I say is true of Exhibit 1.

MR. MOREY: At the end it gives us thirty days in which to submit written comments, I believe, which we did.

MR. EINSTEIN: If you will look at the last page, the end of the first column, Exhibit 1 --

THE COURT: Column 1?

MR. MC MORROW: Yes. The last paragraph.

THE COURT: Will you please read it to me because I do not see it.

MR. MC MORROW: "Any interested person may within thirty days from the date of publication" --

THE COURT: Where is that? Page what?

MR. MC MORROW: Last page, your Honor.

MR. MOREY: Page one.

THE COURT: After the regulation --

MR. MOREY: 17 -- 178.

MR. MC MORROW: The number is in the left-hand corner of the -- it may be obscured by the staple.

THE COURT: Oh, I see it. All right.

MR. MOREY: Your Honor, this is what happened. They published a proposal in the Federal Register and they told us we had thirty days to give them written comments based on what they had put in the Federal Register. They did not tell us anywhere here in the Federal Register or anywhere else -- and we intend to offer evidence on this -- as to what the factual basis was which underlay this regulation that was in here.

Now, they have brought forth a massive administrative record. They now tell us that this is what their factual basis was.

What we are complaining about is that at the time we had no idea what it was about.

THE COURT: Did you ask them?

MR. MOREY: I don't recall that we did ask them, your Honor. Their procedure was not such that we would have gotten anything at the time. There have been subsequent reforms in their procedures. And we

refer in our brief to the fact they now are supposed to -- and routinely do provide all this material. But at that time it was not done.

THE COURT: You see, in the production they say a good deal indicating that they already have the material.

For example, at page 177, column 1, the Agency has been and will continue to be receptive to scientific data.

Adequate processing pyrometers or alternative pryometers for any individual species or smoked fish.

MR. MOREY: What they are saying -- we could give them some more if we had it.

THE COURT: They also indicate that they have much. And the earlier part of it indicates that there is a history here going back to 1963, some seven years earlier -- six years earlier. And the second paragraph they are talking about the suggestion and recommendation of your commercial fisheries and the Department of the Interior.

MR. MC MORROW: Your Honor, in that regard, I just want to note that the --that the Bureau of Commercial Fisheries was the predecessor to the National Marine --

THE COURT: What?

MR. MC MORROW: They were the predecessor of the National Marine Fishery Service. At that time it was known as the Bureau of Commercial Fisheries.

MR. MOREY: We don't dispute that.

MR. MC MORROW: Just to clarify the picture.

THE COURT: Well, I was just wondering.

Yes?

MR. MOREY: Well, anyway, your Honor, our basic contention is that under the practice at that time, this procedure, which included a lot of research done by the Food & Drug Administration for the Food & Drug Administration is -- as well as this vast collection of scientific articles, was not available to us. All we had was this document here which states everything in very -- a very conclusory form. And we believe that the --

THE COURT: Yes. But, I take it, it wasn't anything that was really anything new or shocking.

MR. MOREY: Well, the -- some of the scientific articles were published. I don't know whether or not they have all of the published ones there. We have no idea of just the one that they are relying on. Some were research that was done for them and that we

had no access to at all. They are now saying --

THE COURT: The question is not whether you had access to it, but whether it was furnished and constituted a foundation that supports the action that they took.

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MR. MOREY: The cases we are citing here is that we should have access to it.

THE COURT: You never sought it.

MR. MOREY: We didn't seek it only because the Agency -- under the Agency practice there was no chance that we would have gotten it then. And these cases also do indicate --

THE COURT: I don't know how you can very well say that. I mean the answer in most cases is like that in the City of Washington, that it is full of courts and judges, and if there was something that was essential to the development of adequate and proper administrative action, I should suppose that counsel -- whether it be Washington or not -- solicit ingenious ways that they wouldn't know how to get it out of the Government.

MR. MC MORROW: Your Honor --

THE COURT: If there was a reason that they wanted to, and wanted to --

MR. MOREY: And the other part of it is this. As I indicated before, we considered these to be the regulations that -- it is only subsequent to this that we have had Supreme Court cases that the Government has been referring to the -- to the Nutritional cases -- and in that case, by the way, we have a quote from it in here. That was based on a rule-making proceeding in which all of the scientific evidence that the Government was relying on was made available to the opponents of the regulations for their review which didn't happen here.

I think it's distinguishable on that basis.

MR. MC MORROW: Your Honor, I would like to make two points. First of all, some of the cases which were cited by Mr. Friede inhis discussion -- I think Abbott Laboratories -- were in fact before the regulations. And secondly, this thing didn't happen in a vacuum. Over a period of six years there was an enormous amount of research by a rather limited group of people who knew each other. There was quite a bit of comradeship in relation to the people that knew the work that they were doing. A lot of work was being done by the Bureau of Commercial Fisheries in which they were attempting to do this research to

accommodate the desire of the industry, the need of the industry to produce a product and the concern with the safety of the public. And a lot of work that was done by that agency is the very agency that Mr. Eklund is employed by, and which has a good deal of interrelationship with the industry. They have a constant rapport with the industry. The industry over this period of years knew what was happening. The research was being done by some state laboratories which worked with individual smoked fish processors. The industry knew very well what was going on.

MR. MOREY: It may well be that the National Marine Fishery Service -- the Bureau of Commercial Fisheries thought they were protecting the industry. But we intend to offer testimony from experts who were working with us at the time that they did not have access to this material.

MR. MC MORROW: Your Honor, if experts were working with them at the time --

THE COURT: I take it, what you are saying is that the regulations cannot stand because it was not accompanied by discovery, and without more --

MR. MOREY: Your Honor --

THE COURT: Because if what you say is true

of this regulation, would it be true of any and every regulation which is dependent to any significant extent on undisclosed material which indicated back into the dark and dismal span of time and -- that is represented by any vast 200-year-old government establishment.

MR. MOREY: Your Honor, I am not asking that the regulation be excised from the Code of Federal Regulations. I am just asking that it not be taken as the Gospel, as Mr. McMorrow wants.

THE COURT: Not be --

MR. MOREY: Taken as the Gospel.

THE COURT: Well, there is only one way to take it. It's either there and real and determinative or it's not there. Because I think -- I take it, it's already been determined that such a regulation,in spite of what Judge Doyle said, is part of thelaw. And I would certainly be disposed so to treat it. This is -- I mean, it seems to me, the ADC administrative law that if the administrative body exists, the very purpose of bringing general legislative considerations into specificity of operation, it does it through the option of regulations under adequate rule-making procedures. And if done so -- and that is -- it appears

to me to settle the matter in administrative law concepts unless the regulation is seen on its face to be outside the regulational authorization of the law or is manifested by the service or unsupported by anything of record.

(Continued on next page.)

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MR. MOREY: I would respectfully disagree that this was adequately promulgated. I think that is the —

THE COURT: It is promulgated. I don't think they adopted them.

MR.MOREY: In terms of what was available to us and whether we really had a meaningful opportunity —

THE COURT: What you're saying then is that when you were faced with a proposal to adopt, you set a manufacturing standard, such as that in the Government, and you must make discovery of everything on which it relied and direct your attention to it.

MR. MOREY: Which the regulation now provides that they must do. The FDA's own regulations say they have to do it. They didn't at the time. I believe the cases that we have cited in here also support that their failure to do that, make an inadequate promulgation to a substantive rule. I am not challenging that they could have a substantive rule if they promulgated it and they let us see all this and we have been able to overcome it and under these circumstances I don't think it should be regarded as a substantive rule.

THE COURT: Well, isn't that something which if it was a defect in procedures leading to the adoption of a rule, and that is, you were denied due process in

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the adoption of the rule because they relied on undisclosed material, failed to confront you with the material, which you will need, then that would have been grounds on which a direct attack could have been lodged against part 128(a).

MR. MOREY: In retrospect --

THE COURT: By a spiel to the Court of Appeals. Look, this was written, it was written in words and figures. Your proposed critical limits and it was either something or nothing. In any event, it was specific, wasn't it?

MR. MOREY: Yes, your Honor. But the FDA sets out a lot of specific things --

THE COURT: And at minimum it was a dangerous time bomb, because you don't say, "Well, this is a general guideline," and then set down specific limits. It didn't say on or about or approximately or nearly. It said do this. Do that, do the next thing.

MR. MOREY: Your Honor, there are any number of FDA regulations, as I would show you, that are very specific and the FDA themselves --

THE COURT: You better get them --

MR. MOREY: They say they are interpretive.

MR. EINSTEIN: Your Honor, I think what's been

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said overlooks the administrative procedure act. As I quoted before that under Section 5, U.S.C. 703, we are entitled in this proceeding, since the review that was available --

THE COURT: That is the 700 series, I take it?

MR. MOREY: Yes.

MR. EINSTEIN: Yes.

THE COURT: Just to make it more confusing.

MR. EINSTEIN: Section 5, 703, we're entitled in this proceeding to judicial review because in a civil or criminal prosecution for judicial enforcement of regulations and the scope of review set forth under Section 5, U.S.C. 706, includes whether the regulations are contrary to constitutional rights, power, privilege or immunity. Where it exists, a statutory authority or limiting authority of statutory right, and these are the issues which we are raising here -- I think it is very clear, we say we are entitled, as a matter of fact, to due process, to receive notice. To receive disclosure.

THE COURT: What you're saying then is this: It is void on its face, right?

MR. EINSTEIN: Your Honor, I don't know if we can say it is void on its face. I think we have to

introduce some evidence which cannot come in through Dr. Eklund, but other witnesses, as to what was disclosed to us at the time we went to the agency to deal with this proposed regulation. That will come in through --

THE COURT: That is what, a way of dealing with this?

MR. MOREY: Yes, sir.

THE COURT: Because you say that the basis of the regulation as a right must be treated as limited to that of which they made discovery.

MR. EINSTEIN: Disclosure is the word I would prefer. I think the agency is an agency of the Government under the cases that we have cited --

THE COURT: They are not allowed to operate in the closet with the lights out?

MR. EINSTEIN: It is a constitutional system.

MR. MOREY: We don't ask they be declared void. I think it's reasonable that they be considered only interpretive guidelines as opposed to something that has the force and effect of law.

THE COURT: There is no such place in the law for a critter of that kind.

MR. EINSTEIN: Your Honor, to return to

Dr. Eklund's testimony and I -- the question that triggered all this -- I believe was what is a castrutial botulism and we are opposed to deal with the possibility of injury to health under the -- which we believe is required as a basis for relief here.

Also to deal with the basis for the regulation and also to deal with the issues which can affect your Honor's decision as to whether or not an injunction is warranted.

You may find that a regulation or a statute has been violated, but you may still exercise discretion to the situation to withhold relief. This testimony bears on all of these issues.

MR. MC MORROW: Your Honor, getting right down to the testimony, it seeks to challenge the regulation. There is just no way to hide that fact. They are attacking the regulation and they are attempting to introduce live testimony to do so.

We do not quarrel with their right to get review. We say it is limited to the materials for the agency.

MR. EINSTEIN: Before the agency, but not before the people who are being regulated by the agency.

MR. MC MORROW: Your Honor, there is no evidence that they sought to get that material. We suggest

that they were well aware of the research that was going on.

MR. EINSTEIN: He doesn't have evidence to prove it. We are prepared to put on the witness stand witnesses to prove the contrary --

MR. MC MORROW: That goes to the record, not to the validity of the regulation.

THE COURT: There is a point at which you better start then.

MR. EINSTEIN: We'll be glad to put on those witnesses who participated in the agency's process and certainly we can do that. If your Honor prefers that as a method of procedure.

THE COURT: I don't know. It is your case.

MR. EINSTEIN: All right, let's put on another witness.

THE COURT: Yes, sir?

MR. MC MORROW: I take it that you are ruling on our objection to his testimony at this time --

THE COURT: I think that the testimony that Dr. Eklund is about to give us is almost certainly irrelevant, unless the defendants are right that the regulation is invalid and at that point I think it becomes irrelevant, but not because of what Dr. Eklund

says.

I really see no place for testimony on those issues until the regulation is treated as having regulational validity and it comes before a tribunal, which is competent to try out the issue of whether it should be altered, amended or repealed. Not in this tribunal here. All we are concerned with, as I understand it, as far as you say, whether it is just a general prior directive in a general area occupied by the industry. They should do a little better. They might do this and -- or if you choose, they will abide by it. It it is the latter, whether it has been validly adopted --

MR. EINSTEIN: That would still, I believe, not rule out Dr. Eklund's testimony and whether there is a reasonable possibility of injury to health. I think to determine that --

THE COURT: That is for the people who are in charge of administering this law to determine. It isn't for us to, because the FDA is full of people who are professed to be experts in the field of their supervisory authority. It is for them, out of their experience, which they're paid to have, to evaluate this kind of material and act on it.

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The case comes to a court only when we're trying to determine whether the action that they have taken is authorized by a statute and has adequate evidentiary foundation.

MR. EINSTEIN: Your Honor, then it's been our position throughout this litigation as we urged this morning, that in order to prevail, the Government must show more than a mere violation of the regulation. They must show the statutory prerequisites. That is, insanitary conditions and possibility of injury to health.

THE COURT: That just seems to me another way of saying that the regulation is a matter of not at the moment.

MR. EINSTEIN: I think we're entitled to raise in the judicial enforcement proceedings that is before your Honor at this moment.

THE COURT: I doubt it. I think that is the issue we have to decide. If the regulation is the law and must be complied with, then that is that. The question was, "Was it complied with or wasn't it?"

If it isn't the law, it is not going to turn out to be the law, because of Dr. Eklund's testimony, no matter how persuasive testimony is on this particular

spore strain or whatever, couldn't hurt a fly or that it no longer exists, it has phased out.

MR. EINSTEIN: Your Honor, this regulation was based upon scientific knowledge known to the FDA and not disclosed to us in 1970.

THE COURT: That is something which you say you are prepared to show.

MR. EINSTEIN: Now, we have had --

THE COURT: That involves two questions. Are you right when you say that the FDA can rely only on what it disclosed or are you wrong and, second, if you are right, and not enough was disclosed to support the regulation, then again Dr. Eklund's testimony is not going to help him.

MR. EINSTEIN: If in fact there was not sufficient evidence to support the regulation, then I assume what would happen would be Court would declare the regulation invalid and the case would be over.

If I understand the thrust of your Honor's comment, if you agree with our --

THE COURT: I take it that would be the logic of what I last understood Mr. McMorrow to say.

MR. EINSTEIN: I don't think Mr. Mc Morrow quite adopts that.

MR. MOREY: If the regulation --

THE COURT: What?

MR. MOREY: If the regulations were declared invalid, there would still be an allegation under the statute and testimony as to hazard would be relevant on that.

THE COURT: I don't think that the Government would thinK it had a right to proceed effectively in this case without the assistance of the regulation. It doesn't have to be prepared to defend --

MR. MC MORROW: Your Honor, the allegation in the complaint is that they violated the regulation. They therefore violated the statute.

THE COURT: You see, turning back to the Everett case, in that case the man was specifically indicted for violating a statute as made specific by the regulation which was specifically referred to.

Judge Doyle said, "Nothing doing, no matter what the indictment or information said. I'm going to determine this case and give it to the jury on the basis of whether or not they violated the unspecific language of the statute."

The underlying language, that is.

Now, as I understood Mr. Mc Morrow's position

in this case, the Government has not come to court prepared to start from the bare language of the statute and make a demonstration that this is an insanitary condition and therefore has been prepared in an insanitary manner and is therefore enjoined. They considered that was all done in 1969, 1970. It was embodied in the statute and the regulation. They started from there.

Now, as I understand it, that is the manner in which they wish to proceed.

MR. MC MORROW: That's correct, your Honor.

THE COURT: If you want to meet them on some other ground, that is another matter.

MR. EINSTEIN: I want to understand Mr. Mc Morrow's position. Mr. Mc Morrow, are you saying that if the regulation falls, this case is to be dismissed?

MR. MC MORROW: No. If we wanted to, we could have commenced another action -- what I am saying, your Honor --

THE COURT: Cancel the summons, but that's about all. You need a new complaint.

MR. MC MORROW: Precisely. If we want to proceed, I want to make that clear, on the bare language of the statute, we would amend our complaint.

THE COURT: And your proof it seems?

MR. MC MORROW: Certainly.

THE COURT: Because I don't think at this point Mr. Eklund's testimony would be adequate to occasion it, because it would have to be bolstered by testimony that this was an insanitary method of manufacturing.

MR. MC MORROW: That is what the rule proposes and then we would have to go through each case, case by case to determine that.

THE COURT: The rule was promulgated such as this would not arise. It was not to facilitate the Government's proof but to prove the quality of smoked fish.

MR. EINSTEIN: Your Honor, would you like then to ask Dr. Eklund step down and we will call Dr. Bierman?

THE COURT: Stay there for a minute, if you will, Doctor. If you want to submit an offer of proof so it will be clear what we're passing up, then I think you don't have to do it right this instant. But perhaps you, before you let Dr. Eklund escape again to the West Coast, you can sit down with him and prepare and go over the proof that he would have made, so that we can make that part of the record. So that

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the record will be clear about what we passed up.

MR. EINSTEIN: Your Honor, we have a great deal of other testimony besides Dr. Eklund in similar areas as to the parameters which a marketable product could be produced when the processing parameters -- whether the parameters can be achieved by firms in the industries and so on --

THE COURT: Parameters?

MR. EINSTEIN: Can be achieved in commercial smoking operations and I think that what --

THE COURT: In other words, it is two-fold?

MR. EINSTEIN: That's right.

THE COURT: A, as a practical matter, you can't do it day in and day out in a manufacturing establishment?

MR. EINSTEIN: And produce a saleable product.

THE COURT: And B, even if you succeeded, you would never ship a pound of it because nobody would eat it.

(Continued on next page.)

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MR. EINSTEIN: I think the first part A you can do it. But I think it's conceivable that it can be done, I will make that concession, but no one will eat a pound of it, that would be the thrust and we have a substantial number of witnesses on that subject, which, if your Honor rules that it is irrelevant we would of course want to make a substantial offer of proof.

THE COURT: That would raise a sort of question, wouldn't it? Because it would be a little bit like the last step in the sea right fight. You know you can't make them any more than you can make a 250 horsepower automobile, which are obviously a lethal instrument, because a 250 horsepower automobile serves no purpose except to create death on the highway.

But we haven't gone that far. The mere fact -- let's not call it a mere fact, if the fact that a safety standard is such as to make commercial compliance totally impossible, that seems you've got a hopelessly and helplessly unsafe situation which has got to be abated. It becomes a nuisance instead of a product.

MR. EINSTEIN: You jump. You may have jumped if your Honor, and if I may be so presumptuous, because

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we don't have a safety situation that creates any hazard or risk.

THE COURT: That is another matter. All I am saying is that you cannot infer from impossibility of compliance with the safety standard that the standard is wrong.

MR. EINSTEIN: Now, with intent to --

THE COURT: The inference would be that the practice or process or product must be abandoned, because it cannot function safely.

MR. EINSTEIN: We intend to show you it can function safely. That is a good part of Dr. Eklund's testimony. It is a safe product as produced and if the FDA is tilting the windmills in this case --

THE COURT: That doesn't seem to be very fair from where the Bureau of Commercial Fisheries started out in 1969 --

MR. EINSTEIN: Dr. Eklund has had the benefit of seven years additional intensive research in this area and can bring the benefit of that research to us.

MR. MC MORROW: If he has the benefit of this additional research, why hasn't it been presented to the agency along with a reconsideration of the GMP.

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In the regulation they invite, they invite additional study. It was the FDA which spearheaded the research. It was the FDA that stated they were conducting research in the Government --

MR. EINSTEIN: That is a grossly unfair statement and I am loathe to bring up what has happened since the commencement of this action, but we went to the FDA and in fact, we never had the benefit of the additional research or restudy and the question of this hiatus in these things, they turned us down flat cold --

THE COURT: What your saying is, you are inviting the law to come to a halt under a challenge. The answer to that is no. Then you must go on and say, "We hereby file this formal petition, complete with red and blue seals, impresses and everything else, for a reconsideration and amendment to the preceding regulation and we submit in support of it the following studies:" then you submit them.

MR. EINSTEIN: We did that in 1971 with the whitefish petition involving --

THE COURT: You get a mandamus requiring them to act upon that. Because the one thing they can't do is ignore it.

2/2pm mm4

MR. EINSTEIN: And we have asked your Honor for that in effect to direct them --

MR. MC MORROW: They have asked your Honor to approve it.

MR. EINSTEIN: No.

THE COURT: What is that?

MR. MC MORROW: They seem to be asking your Honor to approve the petition.

MR. EINSTEIN: We have also asked that they be directed to act on it.

THE COURT: They can't do it in this Court. The only party before this Court is the United States. I am not allowed to order them around.

Secretaries, they are easy, but they are all shacked up down in Washington. You have to jump down there.

If you jump on them, and make them act on it, if they turn you down, you can review them inthe Court of Appeals. If they are wrong, they get their teeth knocked out, and they're thrown out.

MR. EINSTEIN: Your Honor, I think you do have the power to direct the agency to act on this whitefish petition, and you were granted the power under the Administrative Procedure Act. There is no other

2/2pm-mm 5

remedy that is available to us.

THE COURT: You see, the secretary isn't a party here.

MR. EINSTEIN: Well, the United States has brought this action on behalf of the Food and Drug Administration.

MR. MC MORROW: But under Rule 15, we don't waive sovereign immunity to this.

MR. EINSTEIN: They brought an enforcement action and I think we are entitled to the full range of our rights.

THE COURT: Well, I think we have discussed that in different ways. Now, I think the question is, it seems to me, not whether we can get at the validity of this, because as I understand it, Mr. McMorrow would concede that if you can demonstrate from the record -- we will step back a minute.

If you can show that what has been presented as what is in the record and on the record the underlying regulations are invalid, then you are home.

Now, if that is shown, as I understood, you are prepared to make that offer.

MR. EINSTEIN: I am going to make it right now. If we can excuse Dr. Eklund, I will call Dr. George

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Bierman. Dr. George Bierman?

D R. G E O R G E B I E R M A N, having been called as a witness on behalf of the defendant, having been duly duly sworn by the Clerk of the Court, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Dr. Bierman, state your residence and address?

A 19 Curwin Road, Peabody, Massachusetts.

Q What is your business affiliation?

A I am president of the Herbert V. Shouther Corporation in Boston, Massachusetts.

Q What kind of a concern is that?

A We provide technical services to the food, pharmaceutical and chemical industry and soft goods industry.

THE COURT: And the what?

THE WITNESS: Soft goods.

Q Just briefly, what is your educational background?

A I received my Bachelor's of Science in microbiology from the Rutgers University in 1951. I received my Ph.D. in Food Science and Nutrition from M.I.T., in 1956.

Q Have you had some connection with what I will call the whitefish processing industry over the past years?

A Yes, I have.

2/2pm mm 7

Q And when did that association commence?

A In November, 1968.

Q And how did it come about, just briefly?

A At that time I think the industry in New York had voluntarily ceased processing of chubs due to a directive referred to as Code 10 by the Food and Drug Administration.

And the industry was interested in the technical assistance and evaluating the interpretation of this and improving their general operations.

Q All right, now, were you personally involved in the negotiations and discussions which took place between the industry and the Food and Drug Administration concerning the proposal and promulgation of the so-called GMP's regulations?

A Yes, sir, I was.

Q And did you attend all of the meetings that were held between the FDA and the members of the industry between the time of the proposal and the promulgation of the regulations?

A That is our regulation here?

MR. EINSTEIN: That's correct.

A To the best of my knowledge, I did.

Q For the record, that is Section 128A of 21 CFR?

A Yes.

2/2pm mm/8

Q Now, when did you first learn that there was a proposed GMP regulation as set forth in part 128A?

A October 16, 1969. It was published in the Federal Register.

Q That is when you first learned about it?

A Yes.

Q Now after you learned of it, did you have any contact --

MR. EINSTEIN: Strike that.

Q After you learned of the proposed regulation, were there any contacts between the agency and the Food and Drug Administration prior to the official promulgation of the regulation, on November 13, 1970?

A Yes.

Q And were you personally involved in those contacts?

A Yes, sir.

Q And did you submit on behalf of industry a written letter of comment on the day of May 4th, 1970?

A Prior to that when the proposed regulation was promulgated or appeared in the Federal register in October, 1969, the Association of Smoke Fish Processors, Incorporated, for whom I was a technical representative, members of the industry and also in the National Fisheries Institute commented

2/2pm mm 9

on the proposed regulations.

Then following that, a meeting was requested and arranged through General Fred Delmore of the Food and Drug Administration to review the industry comment.

After a number of attempts to get that meeting set up, it was -- I believe held on April 7, 1970, among representatives of the industry and the National Fisheries Institute.

Miss Mary Dolan was at the meeting and a number of other representatives of the Food and Drug Administration. We reviewed the comments of the industry and the proposed regulations that the Food and Drug Administration had presented in the Federal Register.

At that meeting, General Delmore --

THE COURT: How does he spell his name?

THE WITNESS: D-E-L-M-O-R-E.

At that meeting General Delmore indicated that the Food and Drug Administration would come out with a revised proposal on the GMP. He would also agree it would be appropriate to set up a technical group discussion for some of the technical aspects of the GMP that the industry was proposing from a practical standpoint in their manufacturing operations.

Q In fact, was that task force ever set up prior

2/2pm mm 10

to the adoption of Part 128A, the GMP?

A The revised proposal was never issued and the task force was never set up.

THE COURT: When you say revised proposals, did Mr. Delmore indicate the nature and extent of the revision, because I had understood, although I hadn't attempted to trace them out, that the final 128A is not identical with the proposed 128A?

THE WITNESS: That is correct.

But, it was the industry's impression from that meeting in April of 1970, that the GMP would come out with additional revised proposals and not a regulation.

That there would be further discussions with reference to the technical aspect of the GMP or proposed GMP.

THE COURT: In other words, they would be somewhat recast and up for grabs again, up for the comment --

THE WITNESS: After a technical discussion, it would be discussed further and there would come out a revised proposal.

This never came to pass. The technical meeting never came to pass. Following that, I believe it was Friday the 13th, in November, that the GMP was officially promulgated.

2/2 pm mm 11

MR. EINSTEIN: I would ask that a letter addressed to General Delmore, on the letter of the Association of Smoke Fish Producers, Inc., be marked for identification, as Defendant's Exhibit B.

THE CLERK: So marked, Defendant's Exhibit B for identification.

(Whereupon the letter addressed to General Delmore was marked as Defendant's Exhibit B for identification.)

BY MR. EINSTEIN:

Q Dr. Bierman, I show you what has been marked as Exhibit B for identification and ask you if you can identify that letter?

A Yes, sir, I can.

Q What is it, please?

A This is our comments as representatives of the Association of Smoked Fish Processors to General Delmore, with reference to the proposed GMP.

Q And did you cause that letter to be sent to General Delmore at the Food and Drug Administration?

A Yes, sir, I did.

MR. EINSTEIN: I offer it in evidence.

MR. MC MORROW: Which one are you referring to?

MR. EINSTEIN: The Association --

12 pm mm 12

THE COURT: May 4th, what year?

MR. EINSTEIN: May 4th, 1970.

THE COURT: Is that what you had --

MR. MC MORROW: It wasn't filed in accordance with the directive which appears on the proposed regulations.

You will note at the end of the special register, the language is inviting comments and specifying that any interested person may, within 30 days of publication of this notice, filing with the hearing clerk of the Department of Health Education and Welfare, written comments.

It was never filed with the hearing clerk. It wasn't sent to the hearing clerk. And by its own termand consequences is not a part of the administrative record.

We would object to it for that reason.

MR. EINSTEIN: If that is true, everything they have in there, except for the first portion, is not part of the administration's record, because they were not filed.

MR. MC MORROW: I'm talking about formal comments on the rule.

MR. EINSTEIN: There is one rule for both sides

2/2 pm mm 13

or we are in a very unfair situation.

MR. MC MORROW: All of the comments which are a part of the exhibit of the administrative record were those that were recieved by the hearing clerk, whom we represent is custodian for these documents and which were received, including comments from Dr. Bierman as a representative of the association.

MR. EINSTEIN: I offer this in evidence, your Honor.

THE COURT: I don't understand, now. In here you say the comments from the industry are just this slim top sheet.

MR. MC MORROW: Those are the comments which were received from the industry, pursuant to the direction to appear, in the notice of proposed rule making.

MR. EINSTEIN: Your Honor, let me put one more question to the witness with respect to this exhibit.

DIRECT EXAMINATION (CONTINUING)

BY MR. EINSTEIN:

Q Dr. Bierman, was General Delmore the individual at the Food and Drug Administration who was designated by the Administration to have the contents with the smoked fish industry concerning this proposed regulation?

A Yes, he was.

mm 14

Q And your meeting was with him pursuant to that designation?

A Yes.

Q And you wrote to him because you understood that he was the contact in the agency that the industry should deal with?

A That's correct.

MR. EINSTEIN: Thank you.

(Continued on next page.)

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MR. MC MORROW: Your Honor, I don't see how this testimony relates to attacking regulations because the agency refused to disclose information, and the letter, itself, is not part of the administrative record.

It ought not to be part of the administrative record. It was submitted subsequent to the time. It wasn't sent to the hearing clerk; it was a letter to the administrative Representative of the FDA, and it is part --

MR. EINSTEIN: It's -- he's an FDA employee, he is not an industry representative.

THE COURT: No. It seems to me that we are going off a little bit in the wrong direction. I supposed that after industry comments came in, that it would not be unlikely that something more would follow than, than the department or the FDA would simply pick the comments and burst into action without more adieu.

That the materials submitted to it might suggest the desirability of inviting formally or informally. Further, meetings and submissions with the industry to see whether completer justice could not be done.

Now, I dont know whether the first part of this

3/1 pmmm2

admission, the formal comments include any comment from Dr. Bierman or the Association, but if so, I take it it's in here.

MR. MC MORROW: Yes, your Honor. It's on Page 16.

THE COURT: 15 of the very first cluster of papers.

MR. MC MORROW: Yes, your Honor.

THE COURT: Now, the other material as far as I have been able to glance through it, and in view of the fact it's very lengthy, I could not have done much with it. It seems to be all dated before '69? This material?

I see the first whole bunch of it seems to be some kind of periodical reporting from '63 up to a date in '68.

MR. FRIED: That's not precisely true.

For purposes of convenience, we have divided it up into the material on which preceded the proposal. The proposed regulations and that material goes back, if I am not mistaken, to articles that appeared in the late 1930's or early '40's; up to the time of the proposal and between that material on which the agency relied appeared between the time of the proposal

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and the time of the final regulations.

THE COURT: The material that the agency gathered for itself?

MR. FRIED: The material that was -- is included in the report is material that was before various individuals in the agency, primarily before Donald Couder.

THE COURT: Donald Couder?

MR. FRIEDMAN: He is a microbiologist with the agency, and working on the proposed regulations at that time, and we have asked him in connection with this case to look through and provide to us those materials that the agency looked at and studied in connection with the proposed regulation.

That is what types of material -- the same types of materials that Dr. Bierman refers to in his letter on Page 3, that is his discussions with the Bureau of Commercial Fisheries, and Dr. Eklund of the BCF Laboratory.

That is relied on by the agency and the industry, and its representatives were fully cognizant of that at the time.

THE COURT: Well, I think I better receive this letter so that I can understand what, if anything,

the industry was doing with respect to dealing with the regulations and to the comments after the discussions with the opening discussions with General Delmore.

Let me look at it.

THE CLERK: That will be Defendant's Exhibit B in evidence.

MR. FRIED: Is that letter admitted, your Honor?

THE COURT: Yes, sir. I should say that in such a case as this, the fact that something is admitted into evidence most of the time is bound to mean that its competency and materiality indeed in some instances relevancy remains an issue of debate, only the debate is now informed because at least we all know what it is that we are talking about, and can see it in a real relation to the issues of relevancy and materiality.

This refers to, and doesn't have much meaning without it, a letter of April 28th, 1970.

MR. EINSTEIN: My next letter, your Honor. Let's mark as the next Defendant's Exhibit, please, a letter of the National Fisheries Institute to General Delmore dated April 28th, 1970.

DIRECT EXAMINATION (CONTINUING)

BY MR. EINSTEIN:

Q Dr. Bierman, I show you a letter of the National Fisheries Institution dated April 28th, 1970, and ask you whether you know if this was sent by the National Fisheries Institute to General Delmore? (Handing.)

A Yes, sir, it was.

MR. EINSTEIN: On the same basis as the prior one, your Honor, I would offer this in evidence.

MR. MC MORROW: I object for the same reason, your Honor, it cannot be a part of the record.

THE COURT: That will be admitted on the same basis.

THE CLERK: That is Defendant's Exhibit C, in evidence.

(Whereupon a letter of National Fisheries Institution dated April 28, 1970, was marked as Defendant's Exhibit C in evidence.)

Q Dr. Bierman, could you tell us a little more of what went on on the one meeting that you did have with General Delmore between the time of the promulgation of the proposed regulation and its adoption?

What was said by the general and what was said by members of the industry, to the best of your recollection?

A Well, as I recall there was a preprinted form

regarding the analysis of industry comments, which the left column listed. The proposed GMP requirements, and then there was spaces in which there were comments from the various industry groups, the Association of Smoked Fish Processors, the National Fisheries Institute, and other members of the industry.

Among the things that were discussed there was the need for identifying species, processing perameters, because all fish cannot be processed in accordance with the proposed GMP requirements.

This was one of the primary things, I believe that was discussed at that meeting. The unrealistic ability of the industry processing all varieties of fish; smoked fish by the 180 degree thirty minutes, three and a half percent salt perameter.

Q Now, Dr. Bierman, I am going to show you what has been produced by the Government -- may I take this, your Honor, -- as the purported administrative record in this case, and I will advise the Court that the Government has provided me with a copy and Dr. Bierman has had an opportunity to examine it before.

And any time, Dr. Bierman, and I direct your attention to what is reported as tabs B through L, excluding Tab A, and all the little numbers in between.

At any time in your discussions with the Food and Drug Administration, concerning the proposed regulation, were you ever shown this material by anyone at FDA?

A No.

Q Were you ever told by anyone at FDA that it was relying on this material in arriving at its formulation of the proposed or adopted regulation?

A No.

Q Did the industry receive any information beyond what appeared in the Federal register and at the one meeting that you had with General Delmore as to the basis of the regulation?

A No.

MR. EINSTEIN: Thank you.

Your witness.

MR. MC MORROW: Your Honor, at this point, could we have a short recess?

THE COURT: Yes.

MR. MC MORROW: Thank you.

THE CLERK: Please arise.

(Whereupon a recess was taken at 3:55 p.m.)

(Continued on next page.)

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MR. EINSTEIN: Your Honor, before Mr. McMorrow cross-examines, I would like to offer in evidence Tabs B through L of the administrative -- purported administrative record, simply for the purpose of identifying what it is that Mr. Bierman says he did not see and was not advised of by the agency.

Of course we are not conceding that that is properly part of the record.

MR. MC MORROW: Your Honor, I would suggest that the entire administrative record be marked as an exhibit, and then --

THE COURT: This is just to guide me through it. I would treat it as a useful index.

MR. MC MORROW: I think referring to it as Tabs B through L is about as clear as we can possibly get.

THE COURT: Yes, but it wouldn't tell me what is in it.

MR..EINSTEIN: Well, there is an index that is, I believe included, that will be helpful.

Is the index included in the copy that was submitted?

MR. MC MORROW: Yes, the materials are all indexed, A through L.

THE COURT: In there somewhere?

MR. MC MORROW: Yes, attached to the affidavit as an index.

THE COURT: Oh, in this?

MR. MC MORROW: Oh, I see. Won't that do as well?

MR. EINSTEIN: Well, I think that the doctor -- I think they both should be marked. It's just for purposes of creating a record, your Honor.

THE COURT: What does it look like, may I see it?

MR. EINSTEIN: That's the same index, your Honor. I'm just holding the index. What I am proposing be marked are the contents of these three envelopes, so that there is a record of what Dr. Bierman says he wasn't shown.

MR. MC MORROW: There is an index attached to the affidavit which accompanies the entire record, right.

It sets everything out, A through L, so for purposes of identifying it, it seems that it's sufficient to refer to it as Tabs B through whatever you want.

THE COURT: All right, that is received in

evidence as the alleged administrative record.

MR. EINSTEIN: Thank you, your Honor.

(Whereupon the contents of three envelopes, referred to as Tabs, was marked in evidence.)

MR. MC MORROW: Your Honor, I want to clarify one point: The record is Tab A through L, and what Mr. Bierman stated he did not see was Tab B through L; correct?

MR. EINSTEIN: That's correct.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Now, Mr. Bierman, you say you have a Ph.D. in food science from M.I.T.?

A That is correct.

Q Have you done any post-doctoral training or had any post-doctoral training?

A Educationally or --

Q Yes, sir.

A Not formally. I've been in the industry for -- since 1956, the food industry and other segments of the manufacturing industry.

Q You stated that you became involved with the smoked industry in 1968, is that correct?

A Yes, sir. I believe it was November, of '68.

Q Was it at that time that you became associated with the Association of Smoked Fish Processors?

A A Yes.

Q And what is the relationship of the company Hubert V. Shouther, and the Association of Smoked Fish Processors?

A We are the technical center for the Association of Smoked Fish Processors.

Q And what does the Association of Smoked Fish Processors represent?

A It represents a group of New York smoked fish processors.

Q It doesn't represent smoked fish processors around the country?

A It at that time represented I believe 85 and 90% of the manufacturing capacity of smoked fish, right up --

Q But you represented only the smoked fish processors in New York area?

A That's correct.

Q Is that correct? So you didn't represent smoked fish processors from the midwest, from the west coast?

A We represented Vita, who had manufacturing operations in the midwest.

Q But other -- you didn't represent any independent

smoked fish processors who have their headquarters outside of New York City?

A No, sir.

Q You stated that you were not furnished with copies of materials B through F as indexed in the administrative record.

Did you ever ask to be furnished with copies of materials which were before the FDA?

A I didn't know they existed, to be honest with you.

THE COURT: No, that wasn't the question. Did you ask for material --

THE WITNESS: No I did not.

THE COURT: -- which would have elicited them?

THE WITNESS: No.

Q You had read, I believe you stated, the notice of proposed rule making in the Federal Register?

A Yes, sir.

Q Had you read the preamble to that document?

A Yes, sir.

Q Did you read the language that states: The Food and Drug Administration acknowledges that adequate times, temperatures and self-concentrations had not been demonstrated for each individual species of fish presently

smoked.

Much work has been done, however, on thermal destruction of spores plus radium botulinum Type E, and today the parameters are the safest in preventing outgrowth of C. botulinum Type E. It has been established that the public health hazard of C. botulinum Type E in smoked fish is not restricted to a single species.

Examples of species found to contain spores of C. botulinum are lake trout, salmon, cod, sable fish, salt sturgeon and white fish.

A Yes.

Q Dr. Bierman, could you presume from reading that language that there was in fact scientific data upon which the proposed regulations were based?

A Yes, sir.

Q Were you independently aware of scientific studies which had been conducted --

A I was aware --

Q (Continuing) -- of the incidence of C. botulinum?

A Yes, I was aware of several of the technical publications that had been -- have appeared in the journals.

Q As part of your business do you review the trade journals and specialized journals dealing with microbiology?

A Some of them, yes.

Q Were you aware of independent studies of work that was being done in thermal introduction of C. botulinum spores?

A I was aware that there had been work done, yes.

Q By whom had that work been done thatyou were aware of?

A The University of Wisconsin primarily. I think Dr. Foster's group.

There were some other people in Wisconsin that had published. I think Michigan State. Doctor Alekovich, I believe, published some work.

Q How did you work about this work?

A By researching the literature.

Q Did you learn about this from your contacts within your profession and within the industry?

A Yes.

Q Did people within the industry and within your profession communicate with each other regarding the research that was going on?

A No, not really. There was very little information transcribed. I -- I -- technical literature went from me to the industry, it didn't come from the industry to me..

Q Did you make any attempt to gather such litera-

ature from the industy?

A No.

Q Well, excuse me, what do you mean by industry?

A The smoked fish industry that I represented, the Association of Smoked Fish Processors.

Q But did you make an attempt to gather together for your own education scientific data and the results of experiments which were being conducted by researchers on C. botulinum Type E?

A Yes.

Q Have you reviewed Tabs B through L?

A Yes, I have.

Q Were you aware of all the published materials which are contained therein?

A No.

Q Were you aware of some of the published materials which were contained therein?

A Yes.

Q As part of your profession as a Ph.D. in Food Science, do you consider it incumbent upon you to remain familiar with research which is being published in professional journals?

A To the best of my ability.

Q Now, with respect to the work which was con-

ducted in the quarterly reports set out in tabs B-1 through 12 -- excuse me, have you reviewed those?

A I have seen those in the literature here. I have never seen them prior to the time they were submitted to me just recently.

Q Now, would you kindly look at the index?

A I don't know whether the index is here or not.

MR. MC MORROW: Do you have a copy of that?

MR. EINSTEIN: I'll hand him my copy, your Honor.

THE COURT: Good.

Q Would you please refer to Tab F-36. Notice the last page, Page 24.

A You asked me to refer to --

Q Yes, the last --

A Did you want me to get the article out here?

Q I will show it to you, it would be easier. Do you note that under "acknowledgement" it says "this work was supported by the U.S. Food and Drug Administration under contracts FDA-6377 and FDA-6344"?

A I see that, yes.

Q Now, this article purports to be from a symposium on food microbiology in Moscow in 1966. Were you aware of that symposium?

A No I was not.

Q You heard Dr. Eklund testify that he was aware of it, --

A Yes.

Q -- that he was present there?

A He's a researcher in the field. I'm not.

Q Now would you agree that a large majority of the articles which are set forth in the index are published in various specialized journals?

I believe they identify themselves.

A Yes.

Q Now, were you aware of the work that John Grakowski was doing?

A I was aware of some of the work he had done, yes, particularly pertaining to the whitefish portion.

THE COURT: Who is this?

THE WITNESS: Dr. Jack Grakowski.

Q With what organization was Dr. Grakowski associated?

A He was with the Anne Arbor Technological Labratory, the Bureau of Commercial Fisheries.

Q That was the predecessor of the National Marine Fishery Service?

A That's correct.

Q Now I ask you to refer to the third page of your letter of May 4th, 1970, which has already been receivd in evidence.

Is it not true that you stated on the third page of your letter "I have spokn with Dr. Jack Grakowski at the BCF Friday, 5/1/70. He advised me that they are planning at least one more innoculated pack with the whitefish, which would presumably complete their studies during the early part or the middle part of June, provided further support data is not felt to be required."

A Yes.

Q You had been communicating then with Dr. Grakowski?

A I had, yes.

Q Were you aware of the research that Dr. Grakowski had done?

A Some of it.

Q Did you ask him about the research that he had done?

A I definitely have. We have tried to get information from him and have been unable to obtain written documentation, much of which I believe has been done but never recorded in formal publication.

Q But you did have occasion to speak with Dr.

Grakowski?

A Yes, sir, I met with him.

Q And you did have occasion to discuss the results of his research?

A Yes.

Q And you have had occasion to review the materials within the administrative records that purport to have been prepared by Dr. Grakowski, have you not?

A I'm not sure which ones have been prepared by Dr. Grakowski. Anyones that he has offered. Perhaps I have seen if they were in journals.

Q Those which purport to be offered by him?

A If they were published in journals, I presume I may have read them.

Q But those which do not appear to have been published in journals, and therefore they were not published in journals, you were in contact with Dr. Grakowski and you did have occasion to discuss with him research which he had done?

A Yes.

Q Now, I believe in your letter on behalf of the association of Smoked Fish Processors, to the hearing clerk on Page 17 of Tab A of the Administrative Record, you state that -- Page 17, I believe it's the second page of your letter

in the middle paragraph.

A Right.

Q You say "Other varieties of fish are even more heat-sensitive. Processing conditions which minimize the necessity for high temperature treatment must be adopted if consumer is to continue to enjoy the products she has been accustomed to. Work now under way bythe Bureau of Commercial Fisheries in several varieties of fish have indicated very encouraging results," et cetera.

A Yes, this was with regard to the nitrite levels and the reducing of nitrite in reducing the processing parameters.

Q But you were familiar with research, then, which had been done which enabled you to make the statement that "Various varieties of fish are more heat-sensitive than others?"

A This was based on industry experience, this is not technical information that was present in the literature.

Q But didn't the technical information in the technical literature include that high temperatures were required to destroy certain amounts of C. botulinum spores?

A Yes.

Q And you state there that you were knowledgeable in the work that was then underway by the Bureau of Commercial

Fisheries on several varieities of fish, is that correct?

A Yes, some of the work I'm sure.

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(Continued on next page.)

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Q I just one to make clear one further point that you -- just to clarify what I believe is your earlier statement that you never asked the Agency to be furnished with copies of the materials upon which they base the proposed regulations; is that correct?

A That's correct.

MR. MC MORROW: Thank you.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Dr. Bierman, had you made some attempts in 1969 and 1970, and even thereafter, to obtain information concerning Dr. Graikoski's work on smoked fish?

A Yes.

Q And did you meet with any success in those attempts?

A Very little.

Q Did you not in fact, on October 8, 1974, write a letter to Dr. -- Mr. Robert W. Schoning, Director of the National Marine Fisheries Service, complaining about your inability to obtain this information?

A Yes.

MR. MC MORROW: Your Honor, I would object to testimony regarding what happened subsequently to the promulgation of the Rules. It doesn't relate

to the administrative record.

MR. EINSTEIN: It is a question of whether he was able to obtain information.

THE COURT: What was the date of it?

MR. EINSTEIN: The letter is in 1974. But it shows a course of conduct of his being refused access to seek information concerning Dr. Graikoski.

MR. MC MORROW: It shows what happened in 1974?

MR. EINSTEIN: Please. Let me finish.

Mr. McMorrow raised an issue that this work was there and all he had to do was ask for it. And here is a history going back from before this regulation was promulgated until well afterwards when we still can't get the information.

THE COURT: No. Because, you see, he has not stated that he asked for it beforehand.

MR. EINSTEIN: Well, I think he did.

Q Did you ask for Dr. Graikoski's work in writing during the period that the regulation was under consideration by the FDA?

A I'm not sure what the timing was, but during that period we had been in contact with Dr. Graikoski and had made attempts to get published literature or work in process from his group, which we were unable to do.

Q And they refused to give it to you?

A That's correct.

Q He refused to give it to you even after the GMP was promulgated; is that also correct?

A That's correct.

Q And that's what prompted your letter of October 8, 1974?

A Yes.

Q All right. Now, during the time that the GMP was under consideration -- that is, between the time it was promulgated for comments and the time that it was adopted -- did you know that the Food & Drug Administration had assembled a mass of documents that are indexed under tab B through L?

A No.

MR. EINSTEIN: Thank you.

RECROSS EXAMINATION

BY MR. MC MORROW:

Q Just two questions:

By whom was Dr. Graikoski employed?

A I believe I just indicated that he was employed by the Bureau of Commercial Fisheries , Ann Arbor Technological Laboratories, in Ann Arbor, Michigan.

Q He was not an employee of the Food & Drug Administration?

A No, he was not.

Q Now, did you ever ask the FDA for the information which -- for the research of the -- the information which was being developed by Dr. Graikoski?

A In refreshing my mind, in our meeting with General Belmore, it was very obvious that work had not been done on species and the processing pyrometers of the variety of species that are smoked by the smoked fish processors. This is the reason that the subject was discussed at that meeting.

Q That is not responsive to my question. Did you ask the FDA --

MR. EINSTEIN: I think it is.

THE COURT: No, it is not.

Q Did you ask the FDA to be furnished with copies or abstracts of the materials for the research which was being conducted by Dr. Gaikoski?

A I don't believe I did; no.

MR. MC MORROW: Thank you. I have no further questions.

MR. EINSTEIN: No further questions.

THE COURT: You may step down. Thank you.

(Witness excused.)

MR. EINSTEIN: I call Mr. Richard Morey.

RICHARD STEPHEN MOREY, called as a witness, being duly sworn by the clerk of the Court, testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Morey, what is your occupation?

A I am a lawyer.

Q When and where did you graduate from law school?

A Columbia University, School of Law, 1966.

Q What did you do after graduation?

A I clerked for one year for Judge Waterman on --

THE COURT: With whom?

THE WITNESS: Judge Waterman, United States Court of Appeals for the Second Circuit.

Q What did you do after that?

A I became an associate with the law firm of Covington & Burling, in Washington, D.C.

Q Did you have any area of expertise or specialization while you were with Covington & Burling?

A I did.

Q What was that?

A Food & Drug law.

Q Did that include practice before the Food & Drug Admnistration?

A Yes.

Q And is that a specialty which you have continued right up until the present time?

A Yes.

Q And in1970 -- 1969 and 1970 -- were you familiar with the practices of the Food and Drug Administration?

A Generally, yes.

Q All right. You have heard the testimony here, of course, as to the material, tab B through L, of the so-called administrative record?

A Yes.

Q Are you familiar with the agency's practice during the time that the regulation was proposed as to whether a request for the production of that material would have been honored by the agency?

A I guess the best answer I can give is based on my experience with other similar proceedings. I would have thought it extremely unlikely that they would have done it.

Q Now, Mr. Morey, I show you a letter dated December 23, 1970, on the letterhead of Covington & Burling --

MR. EINSTEIN: And I ask that it be marked for identification first.

THE CLERK: So marked Defendant's Exhibit D

for identification.

Q I ask you if you can identify this letter and describe to the Court what the letter is.

A Yes, sir. This is a letter which I prepared on behalf of the National Fisheries Institute for the final quarter promulgating Part 128A, which was published in mid-November, 1970.

Subsequent to that we had a meeting again with representatives of the Food & Drug Administration to indicate the industry's continuing concern with the requirements in these regulations. This letter is basically a confirmation of the position we took at this meeting with the Food & Drug Administration shortly after the promulgation of the final order.

Q What is the nature of the letter in effect? Some kind of petition to the FDA?

A I would regard it in the nature of a petition for reconsideration.

5/2

Q And do you have any knowledge as to whether such a petition should properly be included in the administrative record?

A In my opinion, it should be. An FDA present regulation would require that it be so included. I offered it -- pardon me. The present proposed regulation.

MR. EINSTEIN: I would offer the letter in evidence, your Honor.

MR. MC MORROW: May I see it?

MR. EINSTEIN: You have had it.

MR. MC MORROW: This one?

MR. EINSTEIN: Yes. We have given it to you.

I think it has been pointed out that the administrative record or part of it is tab D, and that letter perhaps should be marked Exhibit E.

THE CLERK: We didn't mark the minutes.

THE COURT: Yes, D.

MR. MC MORROW: Your Honor, I would certainly object --

MR. EINSTEIN: Here is the letter.

MR. MC MORROW: (Cont'g) -- to the admission of the letter as constituting part of the administrative record in view of the fact that it was not addressed to the Hearing Clerk and it was not submitted within thirty days after notice of the proposed ruling.

THE COURT: No. As I understand it, this is the -- the suggestion was that it was something in the nature of an application for rehearing. Something of that sort. Reconsideration.

MR. MC MORROW: Which is a legal conclusion by the witness.

THE COURT: Well, I don't know whose ox it gores. I will take it.

Q I should ask you, Mr. Morey, Covington & Burling--

THE COURT: Just a minute.

Q -- at the time was counsel to the National Fisheries Institute in connection with this proposed regulation?

A Yes, they were. They were counsel in connection with Food & Drug matters only.

MR. EINSTEIN: All right. Thank you. No further questions.

THE CLERK: So marked as Defendant's Exhbit E in evidence.

xxx (So marked.)

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Just a couple of questions, Mr. Morey.

You stated that in your opinion it is unlikely that you would have received the record from the FDA. Did you ask the FDA for the record on behalf of the industry or organization which you represented?

A In this particular proceeding, no, we did not.

10 Morey - direct

THE COURT: Just a minute. I have -- let me look at that and see what the general nature is.

MR. MC MORROW: Yes, your Honor.

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(Continued on next page.)

MR. MC MORROW: I have no more questions, your Honor.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Morey, I know you want to get -- it's an uncomfortable place for a lawyer to be there. DId you have any knowledge that the Food and Drug Administration had assembled the massive documents that are now indexed under Tabs A through L?

A At what time?

Q At the time the regulation was under consideration?

A Oh, no.

Q And did you have any reason or motivation for not even making an inquiry on the subject?

A Only what I considered asking them for, for information based on my understanding of their practice, it would be completely futile.

RE-CROSS-EXAMINATION

BY MR. MC MORROW:

Q You were representing the National Fisheries Institute at that time, your law firm was?

A Yes, sir.

Q Did you ask to be furnished with any scientific

data which was before the agency?

THE COURT: I couldn't hear the question.

Q Did you ask to be furnished with any scientific data which was before the industry -- which was before the FDA, upon which the FDA purported to base the regulation?

A As I have said, I didn't because we did not believe there was any chance that they would give it to us. At that point the agency -- the agency simply did not do it.

Q Did you ask who was conducting the research for the FDA and/or who the FDA was sponsoring with respect to this regulation?

A The FDA operated in a closet.

THE COURT: In a what?

THE WITNESS: In a closet.

A I didn't expect to get any sort of information like thatfrom them. They gave us the information that they published in the Federal Register and that is all I thought we were likely to get.

Q But you did not ask them?

A During that proceeding, no.

MR. MC MORROW: That is all.

(Witness excused.)

MR. EINSTEIN: Your Honor, we call Mr. Arnold Friede.

A R N O L D I. F R I E D E, having been called as a witness on behalf of the defendant, having been duly duly sworn by the Clerk of the Court, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Friede, you are an attorney at law?

A Yes.

Q And when were you graduated from law school?

A June, 1973.

Q And for how long have you been with the Food and Drug Administratin?

A Since February of 1976.

Q And what did you do between 1973 and February, '76?

A I clerked for one year for Judge Lawrence Lytent (phonetic), a United States District judge in the Central District of California, and from October, 1974, through January, 1976, I was employed as a clerk with the judicial panel for multiple litigation in Washington, D.C.

Q Sir, were you involved in t he assembly of the so-called administrative record which constitutes Tabs A through L?

A Yes.

Q Now, can you tell us what procedures you followed in obtaining the documents that now constitute this record?

A When we first contemplated bringing the action and following your request, I contacted several people in the Food and Drug Administration Bureau of Foods, these people included Taylor Quinn, who I don't know his official title.

He is one of the head compliance people in the Bureau of Food. Donald Couder, a microbiologist in the Bureau of Food. Joe Perret, a compliance officer in the Bureau of Food. I requested that they get -- locate for me a duplicate for me of those materials that the agency considered during the time that the regulation was being considered.

Q Do you know whether Mr. Quinn was with the FDA during the time period that the regulation was under consideration?

A No, I don't.

Q Mr. Couder, Dr. Couder, do you know if he was in the agency during that time period?

A Yes he was

Q How about Mr. Perret?

A I don't know.

Q I see; now, these documents were not all assembled in any one place, they were in diferent people's files,

disbursed throughout the agency; is that correct?

A It is my understanding thatmost of the documents were in one place.

Q What place is that?

A That they were in Dr. Couder's office and he was the microbiologist who was -- one of the microbiologists that was primarily involved inthe FDA evaluation of public scientific literature and the contract work that the FDA had undertaken in the study as to the existence of microorganisms and the heat and solvent requirements necessary for prohibiting an outgrowth.

Q Is that some kind of filing cabinet in Dr. Couder's office or where was it lodged?

A I don't know. I asked Mr. Couder to get the material.

Q I think it is Doctor.

A Mr.

Q Does the Food and Drug Administration have a system for filing documents which it receives and considers in connection with proposed regulations?

A As I understand it, they now have a proposed regulation which would govern such procedures. But, at the time, like most agencies who still do not have such formal procedures, at the time the regulations were under considera-

ation there was no such procedure established.

Nor the agency believed that that procedure was required under the Administrative procedure Act.

MR. EINSTEIN: I move to strike the last part of that answer, your Honor.

THE COURT: It is just a general signal of good faith.

Q Isn't it a fact, Mr. Friede, that some of the documents weren't even anywhere in the agency, they were under the care of people outside of the agency, and you had to ask for them?

A Yes. I was in Wisconsin talking and interviewing a witness who would only be called in rebuttal and I also went to the University of Wisconsin, along with Mr. McMorrow to interview Dr. E. M. Forrester and at that time I requested that he supply me with the materials thathe had prepared under the contract with the Food and Drug Administration

Those materials are included in t he record. They are materials which he prepared for the Food and Drug Administration under contract, and they were not in doctor Couder's files.

Q Were they anywhere else in the agency?

A We could not --

Q To your knowledge?

A We could not in 1976, locate them, no. I don't know whether they arepresently somewhere or not.

Q Now, this index that we have identified and marked I believe as Defendant's Exhibit D, It was not in existence in 1970, was it?

A No, no.

Q That is something you just prepared after you garnered the information from the governemtn and all these different places in and out of the agency?

A After I requested the Bureau to prepare the documents, it was prepared by my secretary, right.

MR. EINSTEIN: May I have one moment, your Honor?

I have no further questions.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Mr. Friede, in the studies which we see from the record, they were done for the FDA, were they not?

A That is my understanding, that they were done on a lengthy contract with the FDA covering several years.

The contract was a response to the '63 outbreak.

Q So regardless of the fact where the records came from, they were contracted for by the FDA?

A Yes. I reviewed the specific -- those documents with Daniel Couder and he assured me that they were indeed

done under -- with the FDA and they were considered at the time.

Q Did Mr. Couder assist you in indexing these materials?

A Well, when I received the documents from the Bureau of Foods they did notcome with an index which referred to tabs. They came with an index just listing the documents and in order to facilitate referral to the documnts, I had my secretary place the tabs on them and type -- retype the list.

So that for example, Tab F-32 would not justbe a title, but would be readily retrieved.

Q Would you characterize this as a good faith attempt by the industry -- excuse me, by the agency to collect together all of the material which it had before it atthe time it made the decision to promulgate the regulation?

ME. EINSTEIN: I object, your Honor.

THE COURT: May I have the question.

(Record read.)

THE COURT: I take it that was your assignment? Wasn't it?

THE WITNESS: That's correct.

A During the course of this particular assignment, which I spent a great deal of time on, I contacted every person

in t he Food and Drug Administration that I could locate, who had anything to do with these regulations. and the people's whose names come to mind are people like Dick Swanson, who was the succe ssor to a genteman by the name of Lenten (phonetic) who was involved with him and he had some material that I went through to try to find what the factual data was.

I had found no -- all of the factual data, which I could find that was considered by the verious people inthe agency, they are in this administrative record.

I found nothing that -- there is no smoking done hiding somewhere in the FDA that undermines the validity of the regulation.

I would have included it in there as well. I excluded nothing of factual data that came to my attention.

MR. EINSTEIN: Our claim is not one of exclusion but rather inclusion, your Honor.

MR. MC MORROW: Thank you.

THE COURT: I think what he said was there is Brady material in there too. That is on they say on the criminal side.

MR. EINSTEIN: I don't question Mr. Friede on a good fait attempt to get everything that he thought was pertinent. I just question him about whther it is part of an administrative record.

THE COURT: I think he said everything that he coudl find out, by inquiry of men who had worked on the regulation, or by their predecessors, who had worked on the regulation or whose predecessors worked on the regulation to gather everything, good, bad, indifferent that was under review at the time in the regulation was adopted.

MR. EINSTEIN: I'm sorry, are you finished?

MR. MC MORROW: Just one more question.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q At the time the regulation was adopted, there was, as has been testified to, no uniform procedure or tregulation for maintaining documents which came before the agency: is that correct?

A That is my understanding.

THE COURT: For maintaining a room for records, making records, is that what you aretalking about?

THE WITNESS: The agency has no closed record policy as they now have. They attempted to use such a policy so if they attempted to adopt such a policy today they could.

(Continued on next page.)

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Q So, the difficulties, the hurdles that you ran into easily piling the administrative records or the materials that were beofre the agencies is one which you run into.

Were you trying to complete the materials which were relied upon by the agency in any rule-making proceeding at that time?

A Well, the regulations arose to an evolutionary process. They weren't dreamed up in one day, and I tried to find -- to try to trace the history of the regulation to see what the kinds of dates that there was before the agency; what that date was, and how the regulations grew, and exactly what was the substance and what was the reason for it all, and that's what I believe is included in Tabs A through L.

Q And would you have to undertake the same efforts were you to compile or gather together the administrative record of any regulation promulgated at that time; is that correct?

A I woujldn't be able to say, but since there was no procedural regulations at that time, I would suggest that I would have to.

MR. MC MORROW: Thank you.

REDIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Friede, you have assembled a large group

of documents which came from people's files in and out of the agency.

Do you have any knowledge as to which of any ofthese documents were actually read and considered by employees of the Food and Drug Administration in reaching the determination to promulgate and then the proposal, and then adopted the regulation?

A Yes, I do.

Q How do you have that knowledge? Were you there in 1970?

A No. But I did discuss the types of material that were relied on.

Q Did you review each of these documents individually with the people and ask them "did you consider this document," and this next document in connection with the proposed regulation?

A No.

MR. EINTEIN: Thank you.

MR. MCMORROW: No questions.

I have no further questions.

THE COURT: All right. We will adjourn now until 10:00 o'clock tomorrow morning.

(Whereupon Court was adjourned at 5:00 p.m.)

* * *

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

----------x--

UNITED STATES OF AMERICA, :

-against- : 74-C-647

NOVA SCOTIA FOOD PRODUCTS, :

Defendant. :

----------x

United States Courthouse
Brooklyn, New York

May 18, 1976
10:00 o'clock A.M.

B e f o r e :

HONORABLE JOHN F. DOOLING, JR., U.S.D.J.

JOSEPH BARBELLA
OFFICIAL COURT REPORTER

Appearances:

DAVID G. TRAGER, ESQ.
United States Attorney
for the Eastern District of New York

BY: DAVID MC MORROW, ESQ.
Assistant U.S. Attorney

-and-

ARNOLD FRIED, ESQ.
FORREST T. PATTERSON, ESQ.
Office of the Chief Counsel,
Food & Drug Administration

JOSEPH H. EINSTEIN, ESQ.
Attorney for Defendant

RICHARD S. MOREY, ESQ.
Attorney for Intervenor, National Fisheries
Institute, Inc.

MR. EINSTEIN: The defendants call Joseph Brownstein.

J O S E P H B R O W N S T E I N , called as a witness, being first duly sworn by the Clerk of the Court, testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Brown, what company are you associated with?

A Acme Smoked Fish.

Q What is your position with the company?

A Vice President.

Q How long has Acme Smoked Fish been in business?

A Since 1955.

Q How many pounds of whitefish a week does Acme Smoked Fish hot smoke?

A Approximately 5-, 6,000 pounds a week.

Q What is your weekly sales volume in hot smoked whitefish?

A 8-, 9,000 a week.

Q How many people does your company employ?

A Approximately 60.

Q Has anyone ever complained to you about botulism illness from hot smoked whitefish prepared by Acme?

MR. MC MORROW: Objection. This testimony is irrelevant.

Q You may answer the question.

A Would you repeat it.

Q Has anyone ever complained to you about botulism illness from hot smoked whitefish prepared by Acme?

A No.

Q What kind of ovens do you have at Acme?

A Gravity ovens.

Q Brick ovens?

A Yes. Correct.

Q All right.

What happens when you prepare hot smoked whitefish to a temperature of 180 degrees for 30 minutes in those ovens?

MR. MC MORROW: Objection, your Honor. I would like the record to reflect that we object to this whole line of testimony on the ground that the Court is precluded from hearing live testimony on this, and the Court is restricted to the review of the administrative record.

THE COURT: Yes. I quite understand the objection. And in admitting the testimony I am not making a final determination that it is substantively competent or material to any issue in the case, but I am satisfied that without its presence in the record it will not be possible adequately to deal with the

very point of law which I understand the Government to make.

MR. MC MORROW: Are we characterizing his testimony, then, your Honor, as an offer of proof?

THE COURT: No. But something very much in the nature of an offer of proof, because I do not exclude the possibility that the nature and content of the testimony might on some possible interpretation of the applicable rules of law become relevant by reason of its specific content. I don't visualize that as likely, but I do not want to exclude it as a possibility.

MR. EINSTEIN: Mr. Reporter, would you repeat the question? I am sure Mr. Brownstein has lost it after our colloquy.

(Record read.)

THE WITNESS: The fish becomes extremely dark in color. The flesh of the fish becomes hydrated, flaky.

THE COURT: What?

THE WITNESS: Flaky. Like in snowflake.

A high percentage of the fish fall to the floor and are unusable.

THE COURT: You mean from the hooks?

THE WITNESS: Yes.

THE COURT: In the ovens?

THE WITNESS: In the ovens.

Q Is the fish marketable?

A In my opinion, no. Not saleable in our market.

Q Now, have you brined fish to an extent so that you could -- you would achieve a water phase, salt level of five percent in the internal loin muscles of the fish?

A Not five. No.

Q What level of salt do you achieve?

A We try to hit 3.5.

Q What happens at -- what has your experience been at 3.5 percent?

A At 3.5 percent we do get complaints from the customers and we do get returns.

Q Do you have an opinion as to what would happen if you brined the fish to achieve a salt level of five percent?

A I don't think our markets would accept it. I feel that the sale of this product would be reduced drastically.

Q What would the effect on your business be if you had to prepare all of your whitefish in internal temperatures of 180 degrees?

A I feel it would be a drastic reduction in the

sale of whitefish. To what percentage, I couldn't say. But I -- I personally happen to like whitefish. I know I couldn't eat it at that level.

Q What would the effect on your business be if you happened to prepare your whitefish to achieve the five percent salt level on the internal loin muscle?

A I thought I answered that question, but -- well, for all practical purposes, we would stop selling whitefish.

Q Now, when you brined the whitefish, Mr. Brownstein, if you attempt to get a five percent salt level internally, is there a difference between the salt internally and what might be on the skin or surface of the fish?

A Logically, in order to get the five percent salt in the thick part of the fish, the thinner part of the fish -- the belly cavity would absorb more salt than the thick part would.

Q And it would even be saltier?

A Yes.

Q Have you recently purchased new ovens?

A Yes.

Q What kind of ovens are they?

A They are electronically controlled, forced-air ovens.

THE COURT: What is that word?

THE WITNESS: Electronically controlled. I called them forced-air as opposed to the gravity oven.

Q These are the most modern and sophisticated ovens available?

A To my knowledge.

Q How many ovens have you purchased?

A Four.

Q What is the cost of those four ovens?

A I don't know exactly, but it's well in excess of 400,000, probably approaching 500,000.

THE COURT: For the four?

THE WITNESS: For the four.

Q Do you know whether you can achieve an internal temperature of 180 degrees for 30 minutes on the whitefish produced in the electronic ovens and still produce a marketable product?

A Not to my own experience, since the ovens are not in operation at this moment.

THE COURT: In other words, you have not put the electronic ovens on the line yet?

THE WITNESS: That's correct. We feel we are -- without being specific -- weeks away or possibly a month away or so from actually being on the line.

MR. EINSTEIN: Thank you.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Mr. Brownstein, you stated that you had difficulty getting a uniform 3.5 percent salt content -- concentration or salt concentration in the fish -- getting the 3.5 percent --

A What?

Q Do you have difficulty getting 3.5 percent salt in the fish?

A We have difficulty in getting a uniform 3.5 percent in all the fish in the particular batch.

Q Are you aware of any special procedures for attempting to get a uniform salt concentration among the fish processing procedure? That is --

A I am not sure I know what you mean by special --

THE COURT: Well, do you know of any techniques that are published or available to you to get --

THE WITNESS: From my own experience, I found out that there are two ways to attempt it. One is to agitate the fish so that it becomes more uniform. So that each fish in the batch will absorb the same amount or closer to the same amount. And the other method is to make your brine so high that while some of them will be -- the least salty will be 3.5, and the others may be well over.

Q Do you in fact agitate the brine solution?

THE COURT: What?

Q Do you in fact, Mr. Brownstein, agitate the brine solution when you brine the fish?

A Not mechanically.

Q In other words, it's done manually only?

A Correct.

Q How often?

A Several times during the night. We have a 24-hour operation.

Q But you could put a mechanical device in the brining tank which periodically would agitate the water or agitatate the brining solution; is that not correct?

A Offhand, I don't know of such a device. I am told that the Food & Drug had recommended such a device.

Q Isn't it not also a suggestive technique or a possible technique to imprive the salt uptake by the fish to a constant salt solution? That is, to add more salt to the water, to the brine solution, as the fish absorbs the salt?

A I have never heard that suggestion before, but it sounds logical to me.

THE COURT: In other words, the point is, to add salt so that you keep the bath at a constant level. Is that it, Mr. Mc Morrow?

MR. MC MORROW: That's correct, your Honor.

THE WITNESS: Except that it occurs to me that you still have the problem of having the uniformity from the -- in the particular batch.

Q But this is in connection with periodic agitation as well.

Now, Mr. Brownstein, do you recall an inspection which was conducted at your plant in October of 1974 by FDA inspectors?

A Yes.

Q I believe the precise --

THE COURT: December, '75?

MR. MC MORROW: October, 1974. From October 21st to 23rd.

Q I have, Mr. Brownstein, a photocopy of the report which was prepared by the investigator who conducted that inspection. He states, Mr. Brownstein, that during his inspection two oven loads, one of whitefish and one of --

MR. EINSTEIN: Excuse me. What page?

MR. MC MORROW: I am on page 2.

MR. EINSTEIN: Thank you.

MR. MC MORROW: This is the inspection report of October 21st to the 23rd, 1974, page 2.

Q In the summary of findings at the bottom of

page 2, the investigator states that the firm did achieve the required time temperature for both species of the monitored fish, i.e., 180 degrees for 30 minutes for whitefish.

Do you recall that, Mr. Brownstein?

A Not specifically. I do recall that -- of the many or several inspections that I did have, and many monitorings that the Food & Drug conducted in our plant, that they -- there was one time that I was able to achieve the temperatures, but I don't remember any other time. And there must have been at least a half dozen other inspection reports.

Q But the fact is that on one occasion you did reach the temperature?

A Yes.

Q Do you recall whether or not that fish was saleable?

A All the fish in the batch were definitely not saleable. Some of them were.

(Continued on next page.)

Q If you cannot recall this particular investigation, how can you recall that all the fish were not salable?

A I don't remember any particular time that all the fish in an oven batch were salable when we attempted to reach the high -- the 180 degrees, while I don't remember that time in particular, I don't remember any time that it was.

Q Are all the fish in any batch that you cook and smoke salable?

A Just about.

Q But you have some loss in almost all batches?

A Sometimes. Depending on the weather.

Q Now, do the ovens which you have been using to date have any form of humidity control?

A No.

Q Do the electronic ovens which you purchased have any form of humidity control?

A Yes.

Q Have you attempted to cook fish at 180 degrees for 30 minutes using the new ovens?

A Not yet.

Q So you have never attempted to cook fish using a humidity control?

A That's correct. I never used the new ovens yet. They are not on the line yet.

Q Is there forced air circulation in your ovens, in the brick ovens?

A None.

Q It's just convection current then?

A Yes.

Q So there's no control -- constant control or constant circulation of the air?

A There is a constant circulation, even though there -- and there is a method of control by how wide the -- On our ovens, we have four doors. And how wide we keep the door open will determine the amount of convection.

Q But you have never attempted to use forced air circulation or forced air circulation controls in the ovens?

A that's correct.

Q Mr. Brownstein, are you familiar with any suggestions which have been made by the Food and Drug Administration as to how you might be able to process your fish so as to cook and smoke them at 180 degrees for 30 minutes?

A We have had several suggestions.

Q Have you attempted to -- Would you please explain what those suggestions have been?

A the normal operation for us in the old type -- in the gravity ovens, is to dry the fish, then cook them, then add color.

THE COURT: Then add what?

THE WITNESS: Color. A smoke. The smoke adds a coloring to t e fish.

Various inspectors have suggested changing the sequence. Not particularly successful in opration on our part. I can't think of any other suggestions they have made.

Q In other words, they suggested smoking while you're cooking?

A Smoking while -- smoking before.

Q Have they made any suggestions about the time the fish are cooked for the period of time and how quickly the heat is raised in the oven?

A No. Not to me. Not that I can remember.

Q Have you ever attempted to experiment with raising the temperature in the oven more quickly than you have customarily done?

A the reason we have --

Q Have you attempted to?

A In our -- Unknowingly, we have. Not deliberately.

Q So you have never attempted to change your heating methods? That is, the time at which you cook the fish and the time during which you dry the fish in the overn, and the time during which you smoke the fish so as to -- with the

variation of these factors, attempted to get the temperature up to 180 degrees for 30 minutes?

A You're asking a logical question that is not based on experience. At least, not on my experience.

At the risk of attempting -- being in a position where I am trying to educate you, the --

Q I can see that I am not a smoked fish processer.

A I can see that, too.

We -- The normal process is to attempt to dry the surface of the fish before cooking, since once you dry the surface of the fish it gets firm and it is able to support the weight of the fish. the suggestion you are making has a tendency -- has a tendency to cause the fish to fall if you attempt to cook the dry -- If you attempt -- If you apply too much heat to the fish before the fish are dry on the surface, they will fall.

Q How are they attached to the smoke sticks?

A They -- May I -- It's difficult to explain. Let me see how do I explain it.

The fish hang by the tail, either through a stainless steel nail usually, with additional means of support from the nail to the hook. And that goes from the nail to the body of the fish.

Q Is there just one nail?

A Yes. On our sticks there are.

Q Have you ever attempted to use two nails?

A No.

Q Have you ever attempted to use clamps?

A We have used clamps on larger fish. Not clamps, no. They call them a double hook. To add additional support to the fish.

Q So there are methods that you can use to provide additional support for the fish which you are not using with white fish?

A Well, it's my belief that we are applying — Excuse me. Am I permitted to ask him a question?

Have you ever seen a fish of the type we are talking about?

Q I believe I have. I have, yes.

A Well, the tail is relatively narrow and you can't really put too much in there, you know, you support the fish. There is not that much room. And to say, put four nails in a tail is just -- It just won't fit.

Q No, I wasn't saying four nails. I was saying two nails and a clamping device. The device that is used on larger fish.

A They are not clamping devices. We do add -- I would like to point out that it's in our interest that no

fish falls. And we do attempt to put as many supports into the fish so that they don't fall. That's cooking at any temperature.

Q Mr. Brownstein, you said one of the problems with cooking at 180 degrees is that the fish dry out and there is weight loss; is that correct?

A I did not say weight loss.

Q I am sorry. They dry out?

A Yes.

Q They lose weight then?

THE COURT: What?

Q Do they lose weight when they dry out?

A Every cooking process is a dehydrating process. And in dehydrating, it tends to lose weight.

Q Mr. Brownstein, are you familiar or have you heard the suggestion that the problem of the drying of the fish and weight loss could be controlled by humidity -- increasing the humidity within the oven?

A Yes, I have.

Q Have you experimented with that?

A No.

MR. MC MORROW: I have no further questions, your Honor.

REDIRECT EXAMINATION BY

MR. EPSTEIN:

Q Is there any reason why you haven't experimented with this humidity control that Mr. McMorrow just asked you about?

A I don't think its feasible to attach that type of operation to the gravity ovens.

MR. EINSTEIN: No further questions.

MR. MC MORROW: I have no further questions.

THE COURT: Thank you.

MR. EINSTEIN: You may step down.

THE COURT: Thank you.

(Witness excused.)

MR. EINSTEIN: The defendant calls Conrad Spitz.

C C N R A D S P I T Z , called as a witness, having been duly sworn by the Clerk of the Court, testified as follows:

DIRECT EXAMINATION BY

MR. EINSTEIN:

Q Mr. Spitz, what is your occupation?

A I smoke fish.

Q What is the name of your company?

A Rego Smoked Fish Co., Inc.

Q How long has Rego been in business?

A Since 1949.

Q How many pounds of white smoked fish do you hot

smoke per week?

A I would say between 750 and 1,000.

Q What is your weekly sales volume in white fish?

A Smoked white, a couple --

Q Dollar volume?

A Dollar volume going out?

Q Yes.

A I would say a thousand, twelve hundred.

Q How many people --

THE COURT: How many?

THE WITNESS: A thousand to twelve hundred dollars.

Q How many people do you employ in your plant?

A There are two officers and two employees at Rego Smoked Fish Co., a total of four.

Q Has any --

THE COURT: A total of how many?

THE WITNESS: Four.

Q Has anybody ever complained to you about botulism illness from hot smoked wite fish prepared by Rego?

A No.

MR. MC MORROW: Your Honor, I object again to this whole line of testimony on the same grounds that I objected to the last witness. It is irrelevant, and

9 Spitz - direct

the Court is restricted to the record.

THE COURT: Yes. Same ruling.

Q What kind of ovens do you employ?

A Gravity.

Q What happens when you prepare hot smoked white fish to achieve a temperature of 180 degrees internal?

A The skin comes off. They break open. You can't sell them.

Q Have you brine fish to achieve a 3.5 per cent water phase salt level in the internal loin muscle?

A I have.

Q What has been your experience with fish brined to that level?

A People bring them back. We have to return the money.

(continued next page)

HR:em

Spizz - direct

Q What would be the effect on your business if you had to prepare all of your whitefish after 180 degrees internal temperature up to thirty minutes?

A I would have to stop smoking whitefish.

Q What would be the effect on your business if you had to prepare all of your whitefish at a 3.5 per cent salt level or more as measured on the internal loin muscle?

A We could probably sell some. I can't say at this time how many.

Q And if you had to brine it to achieve a five per cent salt level in the internal loin muscle, what would happen?

A We wouldn't be able to sell any whitefish.

Q Have you investigated electronic ovens?

A Yes.

Q Have you considered buying them?

A No.

Q Why not?

A I don't do that kind of business. I don't have that kind of money.

Q You can't afford them?

A Positively not.

Q Thank you.

MR. EINSTEIN: No further questions.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Have you ever attempted to -- strike that.

The types of ovens you have now are gravity ovens?

A Yes, sir.

Q Do you have forced air circulation within the ovens?

A No.

Q Have you attempted to experiment at all with increasing the humidity within the ovens?

A No.

Q Are you aware of suggestions that fish can be cooked to 180 degrees for thirty minutes with the proper control of humidity and temperature?

A Only from hearsay.

THE COURT: What is that?

THE WITNESS: Only from hearsay, your Honor.

Q But you never attempted to do so yourself?

A No.

Let me make an exception. We have tried when the fish have been too dry, we have tried hosing them down with a hose with city water. But it doesn't work out. I think that's creating humidity after a fashion.

Q I beg your pardon?

A I think that's creating humidity after a fashion, hosing down the fish.

Q After a fashion?

A Yes, but it doesn't do too much good.

Q But you haven't attempted to control the humidity in the oven while you're cooking the fish?

A No.

Q Mr. Spizz, do you agitate the brine solution while the fish are being brined?

A Yes, we agitate. We stir it on occasion, yes; I mean like every hour or so. But when we are not there, we can't. But when we are, we do.

Q So there are long periods you do not stir it?

A Yes.

Q Now, Mr. Spizz, do you recall an examination of your plant by the FDA on May 6, 1974?

A I don't remember the dates. I recall an examination.

Q According to the report which was prepared by the examiner at that time, Edward Morocco -- this is on page eight of the EIRR, you stated at the outset of the inspection that you were not able to reach temperatures as high as 180 degrees without ruining the product. But, however, during

the monitoring of two of the seven fish, it did exceed 180 degrees for 30 minutes.

According to Mr. Morocco, the firm stated to the investigators that they did not cook the fish at higher than normal temperatures for the investigatoir's benefit, since you couldn't afford to purposely ruin the fish to meet a higher temperature.

T he investigator stated at the conclusion of a smoking operation, you stated that although the two fish appeared to be slightly darker than what would have been considered perfect, the fish were definitely saleable.

Do you have any recollection of that conversation?

A No.

MR. MC MORROW: I have no further questions.

MR. EINSTEIN: No further questions.

THE COURT: You may step down.

THE WITNESS: Thank you.

(The witness was excused.)

MR. EINSTEIN: I call Stanley Suttenberg.

S T A N L E Y S U T T E N B E R G, having been first duly sworn by the clerk of the court, testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Suttenberg, what is your occupation?

A I am in the smoke fish business.

Q And what is the name of your company?

A Montrose Smoked Fish Company, Inc.

Q And how long have you been in business?

A Since 1938.

Q And how many pounds of whitefish do you hot-smoke a week?

A Approximately six thousand.

Q And what is your weekly sales volume in whitefish?

A Approximately eight thousand dollars.

Q And how many people do you employ?

A Twenty-three.

Q Has anybody ever complained to you about botulism illness from hot-smoked fish prepared by Montroe?

MR. MC MORROW: I want the record to reflect I object to this testimony for the same reason.

THE COURT: Same ruling.

Q What kind of ovens do you use?

A Brick gravity ovens.

Q What happens when you prepare hot smoked white-

fish at internal temperatures of 180 degrees in those ovens?

A The fish, first of all, become much darker than they normally would. The bellies spread apart. The fish have a tendency to shrivel. And under those circumstances it would be almost impossible to market the fish.

Q Do some of the fish also fall on the floor?

A Yes, a certain percentage do fall on the floor from the high temperatures.

Q Have you brined fish to an extent that achieves a water phase of salt content of 3.5 per cent in the internal loin muscle?

A Yes, I have.

Q What has been your experience when you brine fish to achieve this level?

A Our customers complain it's salty and we do have some returns.

Q W hat would be the effect of your business if you had to prepare all of your hot smoked whitefish at 180 degrees internal temperature?

A I don't think we would be able to sell whitefish.

Q What would be the effect of your business if you had to prepare all of your hot smoked whitefish at a five per cent salt level in the loin muscle?

A It would be impossible to sell it at that

percentage.

MR. EINSTEIN: I have no further questions.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Mr. Suttenberg, what type of ovens do you have in your plant?

A Brick gravity ovens.

Q You do not have any electronic ovens?

A No.

Q Are your ovens furnished at all with any form of humidity control device?

A No.

Q It has no steam injection?

A No.

THE COURT: No what?

MR. MC MORROW: Steam injection.

Q Are they gas fired?

A Yes.

Q Is there forced air circulating within the oven?

A No.

Q Have you ever attempted to experiment with controlling humidity within the oven?

A Not the humidity, but we have made experiments.

THE COURT: But you have made what?

THE WITNESS: Experiments.

Q That controlled the humidity?

A I said no.

Q But not that?

A No.

Q Are you aware of suggestions, any suggestions which have been made by the FDA or otherwise, that fish, marketable fish can be processed at 180 degrees for thirty minutes with proper accommodation of steam, forced air and heat?

A I have heard the Food and Drug say that.

Q But you have never experimented with those techniques?

A No.

Q Is it true that some of the fish that you brine in a solution have a salt content in the water phase of the loin muscle of 3.5 per cent?

A Yes.

Q Does it sometimes exceed 3.5 per cent?

A Yes.

Q How high does it go?

A Oh, it could possibly go as high as four. It's all according to how strong you make the brine.

Q Now, when you brine your fish do you agitate

the brine solution periodically?

A Yes, we do manually.

Q Have you attempted to use mechanical devices?

A No.

Q To brine it at specific periods of time?

A No. We do it manually at specific times.

Q During the cooking and smoking process, Mr. Suttenberg, do the whitefish ever achieve 180 degrees?

A There have been a few that have achieved it.

Q Have you attempted to experiment with the sequence of the cooking and smoking operations?

A Yes, we have.

Q Have you experimented with the time within which you raised the temperatures in the oven for both cooking and smoking operations?

A Well, we have reversed the procedure, not necessarily the time. But we have reversed the procedures of the cooking and smoking where we smoke first and then cook.

Q Hav e you ever attempted to bring the temperature up faster than you have in previous -- in your customary practice?

A We have, with the next result of most of the fish falling on the floor when you try to bring it up immediately.

Q But have you experimented with different gradations?

A We have made many experiments over the years and none of them really worked out.

Q But you never tried this accommodation with humidity controls?

A No.

Q Now, do you recall in the examination of your plant which was made by Food and Drug Administration inspectors on April 16th through 18th of 1975?

A I don't specifically remember that one, but if you recall, I will recollect.

Q Well, I can't do much more than simply state that they conducted an inspection at that time.

The results of their inspection indicated that your firm did indeed fail to maintain --

MR. MOREY: What page, please?

MR. MC MORROW: I am reading from page three and then the table which is page 13-A.

Q -- that the firm did in fact fail to achieve 180 degrees for a minimum of thirty minutes; but they note that many of the fish did reach 180 degrees and were held --

MR. EINSTEIN: I object to his characterizing what it says in a document that is not in evidence, that's not marked.

THE COURT: Well, he can show it to the witness,

but I don't think we ought to get too many of these into the record.

MR. EINSTEIN: What page?

MR. MC MORROW: Reading from the table, pages 13 and 13-A, table 3, which is the results of the monitoring.

Q And I draw your attention to the fact that many of the whitefish which were monitored appeared to achieve a temperature which was in excess of 180 degrees and hold that temperature for a period of time which, while they may not be thirty minutes, exceed, ten, fifteen, twenty minutes. And I see in one instance it does meet the thirty minutes.

How do you explain that?

A Very easily. We try to get it as high as we could and still have a marketable product. But evidently sometimes when you run that high a temperature it gets away from you and when you close the fish are not marketable.

Q You don't recall the inspection?

A Yes, I do. I said I don't recall that particular -- but if you recollect, I would tell you. And you're asking me and I am telling you what took place. We did try -- we always try to achieve as high as the GMP and still having a saleable product. And in this particular incident we did reach quite high and evidently it started to glow, the fish,

the bellies started to spread and become dark. And when they closed it, we took it out. Most of the fish were not marketable.

Q Do you try and achieve thehighest possible temperature every time?

A Yes, and still have a saleable product.

Q Does this problem occur quite often?

A Pardon?

Q Does this problem occur quite often with the oven, I think the word you used was blows?

A No. But we tried, when the inspector was there. We try to get as high as possible and actually we did not want it to get that -- for the fish to spoil. It's just when we got it that high it was just too late to stop it. In other words, when we were cooking the fish we were not looking to cook the fish at ahigher temperature because the inspector was there. We were looking to cook the fish as high as we can and still have a saleable product.

Q The problem was you were unable to control the temperature?

A Because we cooked it that high. It was too high we cooked it. And at that particular moment it was too late already to do anything about it.

MR. MC MORROW: Your Honor, I have no further

questions.

MR. EINSTEIN: No further questions.

THE COURT: You may step down, sir.

(Witness excused.)

MR. EINSTEIN: We call Mr. Morty Korchin.

(Continued on next page.)

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M O R T I M E R K O R C H I N , called as a witness, having been first duly sworn, took the stand and testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Korchin, you're testifying here today under subpoena; is that correct?

A That's right.

Q What is the name of your corporation?

A Marshall Smokefish Company.

Q And how long has Marshall been in business?

A Since 1946.

Q And how many pounds of whitefish does Marshall smoke per week?

A Repeat the question, please.

Q How many pounds of whitefish does Marshall smoke per week?

A About 6,000.

Q And what is the dollar volume of sales per week in smoked whitefish?

A Roughly about $7,500 or $8,000.

Q And how many people does Marshall employ?

A Sixty.

THE COURT: How many?

THE WITNESS: Sixty.

MR. EINSTEIN: Sixty, your Honor.

Q Has anyone ever complained to you about botulism illness from hot smoked whitefish prepared by Marshall?

A No.

Q And what kind of ovens does Marshall utilize?

A We have gravity-type ovens.

MR. MC MORROW: For the purposes of the record, your Honor, I would like to raise the same objection I have with respect to the past witnesses' relevancy and the limitation of this Court review.

THE COURT: Same ruling.

Q What happens when you prepare hot smoked whitefish at an internal temperature of 180° in your gravity ovens?

A You get a blistering of the skin. The belly part of the fish spreads very widely. You get a cracking of the skin, a breaking of the skin in a great many fish. You get an objectionable dark color and you lose a good many fish. They fall off the hooks.

Q Is the product salable?

A No.

Q And what happens -- strike that.

Have you brined fish to achieve a water phase salt contact of 5 per cent in the internal loin muscle?

A Have I?

Q Yes, have you done that?

A Yes, we have done it experimentally.

Q Have you ever tried to sell any of that fish with a 5 per cent salt content?

A It's not salable.

Q What would be the effect on your business if you had to prepare all of your whitefish at an internal temperature of 180° for thirty minutes?

A I would imagine we would lose a substantial part of our whitefish business.

Q And what would be the effect of your business if you had to prepare all of your whitefish so as to achieve a 5 per cent water phase salt level in the internal loin muscle?

A Not salable. You won't sell the fish.

MR. EINSTEIN: No further questions.

CROSS-EXAMINATION

BY MR. MC MORROW:

Q I'm sorry, your name is Mr. --

A Korchin.

Q Mr. Korchin?

A K-o-r-c-h-i-n.

Q Mr. Korchin, would you describe the type of ovens you have?

THE COURT: What?

Q Type of ovens you use.

A We have gravity-type ovens.

Q And do they have any forced air circulation?

A No, sir, none other than natural air that goes into the oven on a gravity basis.

Q Are they gas-fired?

A Yes, sir.

Q Do you have a method of controlling the amount of heat which is in the oven, circulating in the oven other than through the control of the gas?

A Yes.

Q And opening the doors?

A Yes. We use auxiliary charcoal heat and smoke.

Q So you --

THE COURT: I didn't follow that.

THE WITNESS: We use auxiliary charcoal heat and smoke in the cooking operation.

Q You put pots of charcoal in the oven?

A Right, right.

Q Do you have any form of humidity control within the oven?

A No, sir.

Q Have you ever attempted to experiment with any

humidity control within the oven?

A No, sir.

Q Have you ever consulted any technological experts with regard to attempting to produce a product in compliance with the FDA regulation?

A Are you referring to equipment manufacturers, and so forth?

Q Among others, yes.

Have you consulted with people who are knowledgeable about equipment that you might be able to use in complying with the regulation?

A We have investigated sophisticated equipment, yes.

Q But you haven't installed such equipment?

A No, sir.

Q You periodically agitate the brining solution?

A Yes, sir.

Q Is that done manually?

A Yes.

Q Are there periods of time in which that is not done?

A The brine is agitated manually as a practice in the plant.

Q How often?

A Two or three times in the course of the brining period.

Q Are you familiar with the suggestion that a more periodic agitation of the brine would assist in uniform salt uptake by the fish?

A No.

Q Have you consulted with industry organizations such as the Smoked Fish Association and the National Fishery Institute concerning methods that you might be able to employ to comply with the regulation?

A Yes, sir. There was some very expensive experiments done by Ted Sanford in our plant revolving around various methods of brining. I don't know how long ago, but I guess it must have been a good three or four years ago. They revolved around circulating the brine, agitating, and so forth.

Q This was subsequent to 1970?

A Subsequent to 1970, yes.

Q Now, do you recall an examination of your plant which was made by investigators of the FDA on May 15th through 17th of 1974?

A I don't specifically recall that day.

Q Now, during the course of that investigation, the investigators recorded their observations and they noted during the smoking and cooking phase of the process at least

two of the probed fish --

MR. EINSTEIN: Excuse me. Mr. McMorrow. What page?

MR. MC MORROW: Page 3 of the EIR of 5-15,17-'74.

Q -- reached a temperature of 180° or above for a period of thirty or more minutes.

THE COURT: How many?

MR. MC MORROW: Thirty or more minutes.

Q Do you recall that particular --

A I don't recall that particular incident, no.

Q Do you have any explanation for why that particular batch of fish --

A Well, it's not impossible to get an internal temperature of 180° in the fish.

Q It's not impossible?

A No.

Q And still get a salable product?

A No. You won't get a salable product.

Q Well, do you recall whether or not this specific batch of fish was salable?

A I do not recall any batch of fish that was cooked to 180 which was salable.

Q Do you monitor the temperature of the fish every time you cook them?

A We monitor the temperatures of every stove of whitefish we cook at this point, yes.

THE COURT: Every what?

THE WITNESS: Every stove of whitefish.

Q What was the first word you used, what whitefish?

A Whitefish.

THE COURT: Every?

THE WITNESS: We monitor internal temperatures of whitefish that we cook at this point now.

THE COURT: Every single one?

THE WITNESS: Sir?

THE COURT: Every single whitefish?

THE WITNESS: No, not every single whitefish. Two fish in a stove.

Q How many fish are in a stove?

A Approximately 600 lbs., five to six hundred pounds.

Q Isn't it possible in five to six hundred pounds of fish, there are fish that do reach a temperature of 180°?

A Yes.

Q This inspector noted that at least two of them did.

Isn't that reasonable to suggest that it's possible to reach 180°?

A Yes.

Q You don't know what the temperature is within each fish, do you?

A No.

Q So it's possible that some of those fish reached 180°?

A Yes.

Q And isn't that possible that some of those fish are salable?

A No, it is not.

THE COURT: I think what he is saying is your production isn't generally salable.

THE WITNESS: Production is generally salable and we are talking about now --

THE COURT: And he says you don't know as a matter of fact at what temperatures they were cooked and for how long, except to the extent disclosed by your two to a stove at a time, right?

THE WITNESS: Right.

Q So --

THE COURT: That was your question?

MR. MC MORROW: That is correct, your Honor.

Q So it is -- perhaps it is possible to cook fish to 180° and still get a salable product?

You may be doing it now?

A Every time we have been monitored by the FDA and we have attempted to cook the fish as hot as possible and we may have exceeded 180 in some fish, we have not had any salable fish.

Q But my point quite simply is --

THE COURT: Well, do you make a permanent record of your two to a stove readings?

THE WITNESS: I'm sorry?

THE COURT: Do you keep a record of your two to a stove readings?

THE WITNESS: Yes, we do.

Q At what part of the stove are those fish located?

A There is a probe in the back of the stove and a pr In the front of the stove and there is an ambient in the back of the stove.

Q There is no forced circulation of air in the oven?

A No.

Q Nor is there any attempt to control humidity in the oven?

A No.

MR. MC MORROW: I have no further questions.

MR. EINSTEIN: No further questions.

Thank you.

(The witness is excused.)

MR. EINSTEIN: The defendant calls David Sklar.

D A V I D S K L A R , called as a witness, having been first duly sworn, took the stand and testified as follows:

DIRECT EXAMINATION

BY MR. EINSTEIN:

Q Mr. Sklar, what is your occupation?

A I am the President of Nova Scotia Food Products Corporation, Brooklyn, New York.

Q And you are one of the individual defendants in this case along with the corporation?

A Yes.

Q And, Mr. Sklar, you were here yesterday and you heard Miss Kolaitis testify about some temperature readings she took on packed fish more than twelve hours after cooking?

A Yes.

Q Did you take a reading with a thermometer of your own of the fish at the same time she did?

A I did.

Q And what does your thermometer reading show?

A 39°.

Q Now, Mrs. Sklar, I show you a copy of a letter

which is marked Defendant's Exhibit A and ask you whether this is --

THE COURT: For identification?

MR. EINSTEIN: For identification.

Q And I ask you whether you recall the circumstances under which you wrote that letter?

THE COURT: Did he write it?

Q Did you write it?

THE COURT: Did you write that letter?

THE WITNESS: I did write this letter.

THE COURT: Did you mail it?

THE WITNESS: And I mailed it.

It was written to the U.S. Food and Drug Administration to one of the compliance officers.

MR. EINSTEIN: I offer the letter in evidence.

I have not had a chance to show you this letter, Mr. McMorrow.

(Letter referred to is handed to Mr. McMorrow.)

MR. MC MORROW: For what purpose is it offered?

MR. EINSTEIN: There was testimony about the absence of certain equipment.

THE COURT: The absence of what?

MR. EINSTEIN: Equipment in the plant. And this is a showing of Mr. Sklar's good nature in complying

with the regulations and having done it the day after being advised to do so.

MR. MC MORROW: Your Honor, I just point out that this --

THE COURT: When is it dated?

MR. MC MORROW: August 5, 1975, and that would be subsequent to the first inspection. And I believe the allegations in our complaint alleged that -- certain freezers and refrigerators in the second inspection also lacked indicating thermometers.

THE WITNESS: That was not correct, though. They all had indicator thermometers.

MR. MC MORROW: Notwithstanding what Miss Kolaitis testified to?

THE WITNESS: Notwithstanding what she testified Every freezer and refrigerator had indicator thermometers in our plant after the last inspection.

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MR. EINSTEIN: I offer the letter in evidence.

THE CLERK: So marked defendant's exhibit A in evidence.

Q Now, Mr. Sklar, how long --

THE COURT: Just a moment, please.

(Short pause.)

Q Mr. Sklar, do you recall the circumstances of the inspection prior to that letter and the circumstances udner which the letter was written?

A Which circumstances are you referring to, in connection with the letter?

Q In connection with the letter, Mr. Sklar.

A Well, I didn't refresh my memory on the letter. I just glanced at it. May I see it again, please?

Q Certainly.

(Handing.)

A This was the second letter that I had sent to Mr. Waltris subsequent to the inspection just before this, in July, this letter was dated August 5th. I had written a letter to -- rather, the first. I asked the investigators to kindly give me a record of the temperature that we obtained in our gravity ovens so that I may be able to use that information in order to adjust our processing procedu res. I continued to make attempt and we have been making them all along

to raise our temperatures in an effort to comply with the GMP, while at the same time having a marketable product.

This information was denied me and so I wrote to Mr. Waltris and asked him for it. The letters went back and forth and finally Washington where we got a final answer that this information is going to be denied for the reasons that the Food and Drug Administration had for themselves. Subsequently, a few days later, I had installed these indicating thermometers wherever they were missing and I wrote this second letter.

Those were the circumstances in connection with this.

Q All right, now, Mr. Sklar, how long has Nova Scotia been in business?

A Since 1940. However, this was just an extension of the business carried on by my late father, who started in business in 1920.

Q The business itself, in one form or another, goes back some 56 years?

A That's correct.

Q Are you aware of anyone ever having become ill of botulism from hot smoked white fish prepared by Nova Scotia during the period that it was in business --

MR. MC MORROW: Your Honor, I object to this

line of testimony. It is irrelevant to the question of whether or not the regulation has been violated.

THE COURT: The objection is noted and overruled for the reasons earlier indicated.

A The answer is no.

Q How many pounds of white fish do you hot smoke per week?

THE COURT: What was the answer?

THE WITNESS: No.

Q How many pounds of white fish do you hot smoke per week?

A Approximately 2500 pounds.

Q What is your weekly sales volume in white fish?

A Approximately $4,000.

Q Would you describe the procedure that is followed by your company in the receipt, handling and processing of white fish; as briefly as you can, Mr. Sklar.

A I will try. I think Mrs. Kalaitis gave you a pretty good idea. She left out one aspect of it, however. We receive our white fish in a frozen state. This white fish is produced in Canadian lakes --

THE COURT: Where?

THE WITNESS: Canadian lakes.

A Such as Lake Winnepeg and the Great Slave Lake

in the northwestern territory. The fish arrive in a frozen state and they are put into process by defrosting them. These fish are put into a stainless steel vat under a condition of running cold water for thawing.

In other words, defrosting the fish to make it possible for us to scale them. That means to take the scales off an additionally clean the belly cavity.

All the belly cavities have already been cleaned at the lake. The fish arrive in what we call a vis array.

Q Mr. Sklar, the fish that arrive, are they subjected to any governmental inspection before they even come to your plant?

A The Canadian fish are inspected by the Canadian Fisheries Department and each carton bears a seal of that department.

Q And, I would like to avoid going over what Mrs. Kolaitis testified to --

A I can give it to you if you want to and if I have left anything out that you want to know?

Q Let me ask you this, Mr. Sklar; are the fish subjected to a chlorine rinsing and washing?

A Yes.

Q Would you describe what and how many parts per million of chlorine are used?

A Very simple; after the fish are defrosted they are then -- A chlorine rinse wash is then done. Very simple, we just wheel the vat over to a chlorine station. A mixture of chlorine and water is the extent of upwards of one hundred parts per million. then it is applied to the fish for approximately fifteen minutes or so.

After which the fish are taken to the cleaning table. They are cleaned, placed in a salt brine, all the requirements of the GNP are complied with or attempted to be complied with as far as temperature is concerned, and the strength of brine is concerned. Then the fish are placed in storage in the refrigerator for a period of time to allow the sale to be absorbed by the fish.

Subsequently, and according to the work schedule, the fish are removed from the refrigerator, rinsed or washed out, as you would have it, and hung. That means that each fish is taken and impaled on a nail, a stainless steel nail jutting out on stainless steel sticks which sticks are filled with approximately fifteen or seven or eight fish on each side of the stick to balance it. They are placed on a cage. The cage is a frame.

THE COURT: Placed on a what?

THE WITNESS: We call it a cage or a rack of sorts.

A This is a frame which takes these sticks, approximately fifteen or sixteen of these sticks per oven load. These are overhead cages and they rolled over on head rails and rolled right into the brick oven or gravity ovens.

Prior to putting them in the oven, however, they are partially air dried, either the normal temperature of that particular day or by the addition of some charcoal fire pots which are placed underneath. Plus the application of overhead fans. Much of the purpose of this is to begin the drying of the fish prior to the final drying in the oven, which is a necessary step.

Q Let me interrupt you; I would like you to go back to brining. Would you describe what you do in brining and any difficulties that you may or may not encounter in the brining operation?

A Mr. Einstein, we have always encountered difficulties in proper brining the fish in accordance with the requirements of the GNP. There are several reasons for that:

Number one, fish is a natural product. It is not manufactured. Each fish, almost like people, have different characteristics and these characteristics affect the intake and uptake of the brine, so that we agitate our fish in the accepted manner and that is manually. We know of no mechanical method, as of yet, and incidentally, parenthetically I have

heard other people testify here that the FDA has made suggestions. Never in the course of my experience with the Food and Drug have they ever made a concrete or constructive suggestion as to what I might or might not do.

They merely claim to monitor and to record what they think they have observed.

In any event, the uptake of salt in the white fish is definitely an erratic condition. I have experimented time and time again. I have placed fish of equal size and in an equal position in equal brine. I have done it with big batches and I have done it with small batches. As far as getting salt intake, it is obvious to all, even if you do not know about the fish business, your Honor. A white fish or any other fish has a big back. That part is the loin muscle. Then it has the belly cavity.

If you put three and a half per cent salt, and if you are able to get it uniform, we get threee and a half per cent salt. We also get less than three and a half and more than three and a half per cent. If you get a three and a half per cent salt solution, if it were possible, you have about six and a half to seven per cent in the belly cavity.

It is elementary and there is no way of reducing the seven per cent salt in the cavity to three without reducing it from the loin muscle to less --

Q On an over-all basis, Mr. Sklar, over the past years, what salt content in the loin muscle have you reached?

A We found that we have had approximately two and three quarter per cent on the over-all, on the average, in our white fish. And based on technical papers put out by the Bureau of Commercial Fisheries, written by Dr. Rakowsky. I have seen suggestions of approximately two and a half per cent salt or even two per cent salt that would retard the development of --

MR. MC MORROW: Objection. The witness is not an expert.

THE WITNESS: I didn't say I was, Mr. Mc Morrow. I said I read what Dr. Rakowsky wrote.

Q Now, Mr. Sklar, after cooling, after the fish have been cooked and smoked, do they go into a room for cooling?

A Yes.

Q And are these fish brought down to a fifty degree temperature within the three hours as provided for in the GNP?

A Without question. There has never been any question on that. As a matter of fact, we have the facilities to bring down our temperatures soecifically in accordance and in full compliance with the Good Manufacturing Practices

suggested and advised by the Food and Drug Administration.

Q Now, you heard Mrs. Kalaitis testify yesterday about some fish that she stated, based on her thermometer, were in excess of 38 degrees more than twelve hours after cooking?

A I recall that incident very very clearly.

Q Would you describe the circumstances of that?

A The Food and Drug investigators, during that period of February 23rd to the 26th of this year, monitored lots of fish. In each of these three lots there was no question about complying with the temperature raise, specifically and accurately and even our temperatures were better. In the fourth lot of fish we complied very well with bringing the fish down to 50 degrees within the three hours. As a matter of fact, the fish were down to 50 degrees within one and a half hours. The fish went down to 38 degrees and perhaps 37 and on that particular morning when the investigators had to be there at that time, let's say, closer to the 12 hour period, they would have found the fish to be 38 degrees.

However, during the night, with the employees who pack the fish come in, they raised the temperature of that room in which the fish is stored.

Q Stored?

A Stored. For the purpose of being able to work.

In order for a fish to be 38 degrees, internal temperature, the room has to be considerable colder than the internal temperature, whether it is a refrigerator or oven, always has a lag behind it, the ambiant temperature of that particular environment. Anyway, these fish were packed and then placed in the refrigerator and I found that, 19 hours I think it was, Mrs. Kalaitis said that after the fish were —

THE COURT: How many hours?

MR. EINSTEIN: Nineteen, he said.

A Nineteen hours. That the fish were 39 degrees temperature. Now, allowing for plus two or minus, the variable or tolerance for thermometers, I took objection to the investigator's temperature reading.

However, that is about all I could do.

Q So that the union -- the employees raised the temperature of the room to work in it and packed the fish and that is the cause of any temperature raise?

A That was the cause at that particular time. However, we have since made some changes in our operation to avoid something like this, which we do not consider really, if I may , a serious matter, because there is no doubt in my mind and in everybody's mind in the fish business, all the temperature parameters have a tolerance or safety factor, if I may put it that way.

Q In any event, Mr. Sklar, as soon as the fish are packed, they are then returned to a room where they are kept below 38 degrees again?

A Oh, yes, absolutely.

Q How are the fish shipped out of Nova Scotia?

A What do you mean how?

Q Are they on trucks?

A Well, all our fish is packed in sanitary cartons. There is a carton on the table that I was asked to bring in.

THE COURT: A what?

THE WITNESS: A carton.

A The fish is put into a corrugated carton, your Honor. The fish is taken from the nails, from the smoke sticks, placed in a carton similar to this. These cartons or larger cartons. And it is then either directly deliverd by our employees, in our own trucks, which are refrigerated trucks, which keep the temperatures in accordance with the requirements of the GNP, or we may ship fish on refrigerated over-the-road trucks who come in and pick our fish up. Their trucks are also refrigerated.

Q Have you ever permitted to leave your plant in a vehicle where they would not be maintained at a temperature of 38 degrees or less?

A Now, Mr. Einstein, this happens to be very fre-

quent when people want to pick up fish and they do not have refrigeration. It is the policy of our plant to refuse anyone who does not, who is not equipped to keep fish at 38 degrees.

Q Incidentally --

MR. MC MORROW: Excuse me, I would like to interpose an objection at this point. This testimony we are now hearing does not relate to counter any of the allegations in the complaint. In fact, it is rather far afield and I object to it on relevant grounds.

THE COURT: Yes.

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THE COURT: Yes, it would seem to be beyond the point at which we are interested.

MR. EINSTEIN: I think it goes, your Honor, to the entire question of the safety of the product and how it's handled. And it's essentially laying a foundation for further testimony which we will have in this area --

MR. MC MORROW: Your Honor --

MR. EINSTEIN: -- as to refrigeration and similar matters.

MR. MC MORROW: That's not an issue here. The only thing in issue here is whether or not he violated the regulation, and what other activity he may engage in or whatever business practice he may be engaged in, and whatever other things he may do himself to insure that his product --

MR. EINSTEIN: I won't --

MR. MC MORROW: -- and to the best of his ability to get to the -- get the product to the consumer in a safe fashion is not an issue.

MR. EINSTEIN: I only have a few more questions in this area. I ask you to indulge me.

THE COURT: That's the old story. It's just a small illegitimate baby. But he says he's illegitimate.

MR. EINSTEIN: Well, I believe this is legitimate. I don't want to take a lot of time on it. I think it's a proper area of inquiry for the Court to be aware of, which are the numerous safety factors that are involved in the preparation of the fish, and to demonstrate to the Court that we followed them.

MR. MC MORROW: Your Honor, these things --

THE COURT: I think we are going too far afield. Nobody has suggested that the general practices of the company are not what they should be.

Q Mr. Sklar, let me ask you this. Does your -- have your whitefish been vacuum packed?

A No.

Q Now, Mr. Sklar, what is the frequency of delivery of your fish to your customers?

A Well, it's almost on a daily basis. We deliver five days a week. However, not every customer buys fish every day. Some of them buy three times a week. Sometimes four times a week. And some only once a week. But it is a perishable product and is consistently turning over on a regular basis.

Q Now, Mr. Sklar, I show you this box that has been marked as Exhibit F. And I ask you if this is the box that your company uses -- the type of box it uses in shipping

its whitefish?

A Yes, it is.

MR. EINSTEIN: I offer it in evidence.

MR. MC MORROW: Your Honor, I object to it. I think it has no relevancy to this case. This can continue and continue. And pretty soon we are going to have consumers talking in here. There is no need for this testimony. It is totally irrelevant.

THE COURT: I don't think it really has any particular --

MR. EINSTEIN: It is for the purpose of showing the legend on the box, instructing the -- that the product be kept refrigerated.

MR. MC MORROW: I object to it because it has no bearing whatsoever --

THE COURT: Yes.

MR. MC MORROW: -- on this proceeding.

THE COURT: Yes. It's excluded.

MR. EINSTEIN: I'm sorry. Have you sustained the objection, your Honor?

THE COURT: What?

MR. EINSTEIN: I didn't hear what you said.

THE COURT: Yes, I sustained the objection.

Q Now, Mr. Sklar, do all of your refrigerators at

the present time have indicating thermometers?

A Yes, they do.

Q Everyone of them?

A Every one of them.

Q Did they have such -- did all of your refrigerators have such thermometers at the time of Mr. DeLillus' last inspection?

A The one in '76?

Q Yes, sir.

A Yes, they did.

Q Every one of them?

A Every one of them.

Q Now, what about recording thermometers?

A A few of our refrigerators and freezers do not have recording thermometers. And for the very same refrigerators that have the indicating thermometers --

Q Have you done anything about that situation in recent weeks?

A All I can tell you is that almost coincidental with the serving of the summons from Food and Drug, the recording thermometers were all installed.

Q Every refrigerator now has one?

A Every refrigerator and every freezer.

Q Now, Mr. Sklar, there's been some discussion

about temperature problems in the gravity ovens; is that correct?

A Yes.

Q Do you recall that testimony?

A Yes, I do.

Q Did you at one time have temperature problems in each of the gravity ovens that are utilized by Nova Scotia?

A I'm glad you asked me that question. Yes, I did. It was back in '73 when I -- 1973, when I started to look into the matter of putting recording thermometers on our gravity ovens. And it was in '74 -- 1974 that we had them installed in each and every one of our gravity ovens. This was done in order to comply with the good manufacturing practices. Up until that time we used manual thermometers, the same type of indicating thermometers that the investigators used to monitor the lines in our plant and the finished products. The same thermometers we used in our ovens.

However, in order to comply with the GMP's, we installed these at considerable expense. We were using them. We asked that they be adjusted. We didn't feel they were fully calibrated. And they -- an attempt was made to calibrate them. And in the interim a team of Food and Drug inspectors came into the plant. They used their parameters and they found there was a great difference between what we were

recording on the chart and what they were recording on the dial.

Subsequent to that we called the manufacturer. We advised him in writing and verbally that these temperature recorders were not operating in accordance with the findings of the Food and Drug. We asked them to repair them. We urged them to do so. They dragged their feet and it was in 1975 -- sometime late in 1975 that they finally threw their hands up and said, "We can't do anything about these."

During an inspection in 1975 -- Miss Kolaitis was there also. And her report was that we lacked operable recording thermometers, which meant we had recording thermometers but they weren't operating. Since that time -- since the last inspection --

Q Were those inoperable or non-working thermometers removed by the manufacturer?

A Yes, partially. Before the inspection three of them were removed. And after the inspection the other three were removed. They took three out to see if they could do anything with them.

Q And they were unsuccessful?

A They were unsuccessful.

Q Have you attempted to obtain some new recording thermometers?

A Yes, I have.

Q Tell us about that, please.

A Very simply, we have gone to another manufacturer of a different quality equipment, and we installed subsequent to the last inspection one recording thermometer which measures the temperature of the oven. And it has one problem, to measure the internal temperature of the fish. And we feel if we are successful with this one, then there is no question but that we will repeat the same thing that we did a few years ago and install the balance -- the remaining five.

Q You have six gravity ovens altogether?

A Yes. We also have another type of oven.

Q We will come to that.

What is the cost of this new temperature thermometer per gravity oven -- per oven?

A Per oven it is approximately $1250 to $1500 per oven.

Q Now, Mr. Sklar, are you also engaged in a renovation and construction project or planning one at your plant?

A I'm glad you asked me that.

MR. MC MORROW: Excuse me, your Honor. I must object to this line of testimony for the same reasons as before. It just has no bearing on the question of

whether or not Mr. Sklar has violated the regulation.

If we go into all of this proposed plan, we could be here all day. It just has no bearing on this proceeding. What Mr. Sklar proposes to do in the future simply has no bearing.

THE COURT: Well, I think Miss Kolaitis' testimony reflected that.

MR. EINSTEIN: Certainly did.

MR. MC MORROW: But that has no bearing on whether or not the regulations have been violated. If the -- what he is going to do in the future at some indeterminate time --

THE COURT: It might bear on the nature of the injunctive relief. If you are entitled to it.

Q Would you just very briefly, Mr. Sklar, describe what your -- what you are planning to do? And please be brief.

A I plan to extend the factory in such a way that it will make it more possible for me to guarantee that Food and Drugs requirements, as they are at this time -- so this is what I'm planning to do.

Q What is the project cost of this?

A Costs about $500,000.

Q All right. Now, do you recall -- are you planning

as part of this renovation to tear down some of the existing refrigerators and freezers?

A Yes.

Q Can you show us on the chart that has been marked Plaintiff's Exhibit 4 the area where these refrigerators or freezers will be torn down?

A This refrigerator will be destroyed. This freezer. And this freezer will be destroyed.

Q Indicating 7, 6 and 5?

A And these two will be destroyed.

Q Indicating 8 and 9.

A Mr. Einstein, I don't know whether you are going to allow me to volunteer some information, but I am trying to be helpful here. And you have to keep in mind that I am the defendant.

Q Well, Mr. Sklar, I have some more questions for you.

Now, at the time that the GMP was first proposed, Mr. Sklar, did you offer any comments to the FDA concerning the proposal?

A I wrote the hearing clerk a letter.

MR. EINSTEIN: For your Honor's information, that letter is in the Tab A.

Q Did you also discuss your objection at any

meeting with any FDA officials?

A We had many meetings with FDA officials, both in which I attended personally and those in which I was represented by an association of smoked fish processors and by the National Fisheries INstitute.

Q Now, Mr. Sklar, at the meetings that you attended with FDA officials, did you voice any objections to the proposed GMP's?

A We voiced objections only to those aspects of the GMP's that we felt were unfair and inequitable and arbitrary. And I don't want to usurp the language of the attorneys so I won't go any further. But we did object and object strenuously, but FDA paid no attention.

Q Did you object to the temperature requirements?

A Yes.

MR. MC MORROW: Your Honor, I object to the statement that the FDA paid no attention. He has no knowledge of that.

THE COURT: All I want to know is what did you object to.

Q Did you object to the salt requirements?

A Yes, we did.

Q What did you tell FDA about those two requirements in particular?

A We said that that -- we had -- first, we didn't feel that the equipment that was in existence at the time, and which is still in existence, to a large extent was capable of attaining those parameters as far as temperatures were concerned. And if we did continue using that equipment, we would obtain a non-marketable product. At the same time we objected to the salt -- the high salt concentration because we felt that they were both undesirable from a taste point of view and therefore inedible, and also from a safety and health point of view.

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Q What do you mean by the safety and health point of view?

A Well, the trend in the country today is, so far as mildly salted foods, because of the common knowledge that salt is hazardous and dangerous to people's health, creating hypertension, et cetera --

MR. MC MORROW: I object to this line of testimony. Mr. Sklar is not an expert on the effect of these --

THE COURT: Well, what he is talking about is the professed common knowledge.

Q You may continue, Mr. Sklar.

A Well, I -- You continue, Mr. Einstein.

Q All right. Have you finished your answer?

A I objected to the temperatures and the salt concentration. And I objected to other aspects of the GMP's as well. But it wasn't only my objection, Mr. Einstein. There were a number of people interested --

Q All right. Mr. Sklar, we are only talking about your position.

Since the adoption of the GMP's, have you reiterated your position to officials at FDA that the temperature and salt requirements are impossible of compliance?

A Will you permit an answer without saying yes or

no?

Q I was going to add, if you say yes, I will ask you a question and --

A All right. So it's covered.

We have had in the beginning, in the early days, inspectors from Food & Drug approximately once a year. It was only in the last -- I'd say 10 months that they stepped up their investigation in my plant. In each case, Food & Drug officials called to my attention that I was not complying with the good manufacturing practices regulations. They even called this to my attention when these -- regulations, they call them now -- were guidelines. And in each case I said to them, look, I can't do it technically. And I feel that it is undesirable from a business point of view. I will not have a viable business. I have tried it. I have experimented.

And I might say, your Honor, that I have been in the forefront of the development of sanitation in my plant, vis a vis the industry. I have insituted stainless steel sticks. We were the very first ones to have them. I instituted a control system. I created a laboratory and an in-plant laboratory. I engaged a qualified control man to take in-plant samples so we would know exactly what we are doing. And as I said before, we even put in recording thermometers. Unfortunately, they didn't work.

MR. MC MORROW: Your Honor, I must object again. What Mr. Sklar has done in other respects doesn't bear upon the fact that the -- on the violation of the GMP that we allege, and it is simply not relevant.

THE WITNESS: I will come back to the question, Mr. Mc Morrow.

MR. MC MORROW: I would like a ruling from the Court, Mr. Sklar.

THE COURT: No, that will not be stricken.

Q Will you come back to the question. And I think my question to you, Mr. Sklar, was, what have you told FDA officials since the adoption of GMP's?

A So I told them that we can't do it and I gave them the reasons.

Q All right.

A One moment. And they said, Mr. Sklar, you may go home. They didn't say anything more. They didn't come in and take any legal action. They lulled me and perhaps the rest of the industry into a kind of complaisancy because we just -- this has been going on -- because the GMP was promulgated in '70. And here it is 1976. And now in each and every year -- and in some instances more than once during the year, I went through the same litany with Food & Drug. And

they said, O.K., we will take down everything that you say. And we have hearings. And I have copies of it. And the Food & Drug has it also. And they said, O.K., now you can go home.

Now, if it were an illegal act to do, then Food & Drug had the responsibility to take action.

MR. MC MORROW: Your Honor, I object to this line of testimony. He's not in a position to characterize what the FDA should or shouldn't have done.

THE COURT: He can say if he thinks it be the fact that they were lulled into secure non-compliance.

Q Now, Mr. Sklar, to your knowledge, does your plant -- is it infested with animals or dirt or roaches?

THE COURT: No such claim.

THE WITNESS: No.

MR. EINSTEIN: O.K. I will withdraw the question.

Q Now, at the time that the GMP's were proposed, did you have any understanding as to whether they were tendered as guidelines, or would they be binding on the -- binding regulations in force by law?

A Mr. Einstein, there were guidelines --

Q I would appreciate it if you would answer the question.

MR. EINSTEIN: Will the reporter read it.

(Record read.)

THE WITNESS: It was my understanding --

MR. MC MORROW: I object to this. It is simply not relevant to the question, again, of whether or not he's violated the regulation. How he thought the regulation should be construed --

THE COURT: No. He's not being asked that. He is being asked, as I understand it, if anything, was he given to understand by FDA as to the nature of the GMP.

MR. EINSTEIN: Well, I am asking from any source, to be perfectly honest with you.

THE WITNESS: From all sources?

THE COURT: I am not intersted in what he thought. If he was given any information by the GMP -- by the FDA as to the nature of the -- that would be relevant.

Did you have any understanding from any source?

Q Mr. Sklar --

A Well, I had an understanding from other sources and as well as from FDA. We can include FDA, your Honor, in this.

Q All right. How was it --

A That these regulations were advisory and only

guidelines. FDA has -- did at that time and has only recently in 1975 publicly stated at a public meeting with industry that as long as industry will have gravity ovens, they cannot and will not be able to comply with the regulations.

Q Now, Mr. Sklar, will you tell us what kind of ovens you do have in your plant?

A We have the usual gravity ovens. And the reason they call them gravity is because they are the opposite of forced air in that there is a sort of a little chimney or a -- the word escapes me at the moment. In any event, you have air entering the front part of the oven and will gravitate to the rear and then go out through a --

Q Flue?

A Flue. Right.

Now, this is what we have had in all the years.

Q How many of those ovens do you have?

A We have six.

Q All right. You also have a sophisticated electronic oven?

A You know I have one. Why are you asking me the question. I was coming to that.

In order to comply with the GMP -- this is the thing that bothers me the most, because I have done a great deal in order to comply with the GMP's and I am now being accused

of not doing so.

In order to comply with the GMP, and having done some experimental work in the gravity ovens with humidity and temperatures, and finding that it was not possible to reach the parameters that the GMP requires with a gravity oven, I purchased a sophisticated type of oven which was totally enclosed, environment controlled in many different ways, including humidity control, and a number of different programs for cooking and baking.

Q Mr. Sklar, what was the cost of this electronic oven?

A It cost approximately $70,000 to put in this pilot oven. It is not a very big one, but it can hold approximately 800 pounds of fish.

Q All right.

Now, Mr. Sklar, have you attempted to prepare hot smoked whitefish at an internal temperature of 180 degrees in your gravity ovens?

A We have.

Q All right. And what happens?

A Well, the fish cannot be controlled heat-wise. In order to get 180 degrees in the coldest fish in the oven, we sometimes get 220 degrees in the hotest fish in the oven. There is in these gravity ovens a differential as much as

40 degrees between fish in one part of the oven and fish in another part. This is why Dr. Angelati of Food & Drug said publicly that as long as there will be gravity ovens, industry cannot comply.

Q Now, what happens to the fish themselves when you attempt to prepare them at 180 degrees internal temperature so that the coldest fish, as required by the GMP, is at that temperature?

A The fish gets crisp and -- as if they were being broiled on a fire. We have to remember that smoked fish is a specific item. It isn't taking fish and putting it in the frying pan or in the skillet and putting it on a fire. It is a fish which is completely brown because it has been subjected to a natural smoke. And for that reason it has to hang in mid-air while it is being cooked and smoked.

And what happens to these fish is, if they aren't salt-dried to the right consistency, and you apply heat, they blow.

What do we mean by blow? The belly cavity opens up and almost turns inside out. Something happens to the texture of the meat. It becomes unappetizing looking. No one will go near it. No one will touch it. It cracks. It splits inside and it splits outside. It becomes dehydrated. It becomes a non-marketable product.

Q Now, have you attempted to prepare hot smoked whitefish at 180 degrees internal temperature in your electronic oven?

A We are in the midst of doing experiments of that nature. And where --

Q All right. Have you been able to achieve a marketable product at 180 degrees internal temperature in the electronic oven up until this point in time?

A Mr. Epstein, our experiments are not completed as yet.

Q Well --

THE COURT: No. He asked you to date.

THE WITNESS: To date, not yet.

Q Do you have the same problems as you had with the gravity ovens?

A We are able to be more sophisticated. And I believe that we have the capability of doing something different than we do in the gravity oven. But exactly what it will be has to be determined.

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Sklar-direct

Q Now, have you attempted humidity control in the gravity ovens at all?

A Yes.

Q Does that do anything -- any good in the processing?

A It was nto successful. I know of no piece of equipment that will give me control -- humidity control. And we have done it in order to see whether we can do it sort of manually, such as, for example, putting pans of water over our gas jets and boiling the water, and then getting some steam into the chambers. But because it is not a closed chamber it is not effective.

Q All right. Now, have you brined fish to achieve a level of 3.5 percent water phase salt in the interior loin muscle?

A I have in the past but I must also tell you that we haven't been always successful in reaching that.

Q What has been your experience in selling fish brined to that level?

A It is not acceptable to our clientele. We have economic losses whenever we reach approximately that level.

THE COURT: That's the 3 and a half?

THE WITNESS: Yes sir.

Q Have you in fact been called the Mayor of Salt City by one of your customers?

A Well, you know that because I told you that the other day, Mr. Epstein.

Q So that that has happened?

A Yes sir.

Q Now, what would be the effect on your business, Mr. Sklar, if you had to prepare all of your whitefish at 180 degrees internal temperature for thirty minutes?

A It would be devastating because it would not be confined to the whitefish alone. It would involve the other products that we manufactur.

Q You mean if you couldn't provide whitefish to your customers, you would lose business in the others?

A Yes sir. Absolutely.

MC MORROW: Your Honor, I just want to object to the line of testimony because our complaint restricted itself to an allegation of failure to file the GMP with whitefish processing.

THE COURT: Yes, I understand that. But he is talking about balancing equities.

Q Now, if you had to brine all your fish to achieve a 5. water phase salt level in the interior loin muscle, what would the effect of that be upon your business?

A Doubly devastating.

Q Do you have any opinion of what the effect would be if you were to be enjoined from violating these requirements and the rest of the industry was unaffected?

A Well, very much so. It would be an economic disaster. My trade would all gravitate to the rest of the industry, whichever it is. My entire family's fortune -- I don't mean in terms of high amounts, but I mean whatever we possess would be lost. It would be something terrible.

Q Now, Mr. Sklar, do you recall that during the past week Dr. George Berman was at your plant?

A I sure do.

Q Do you recall that he prepared some fish at 180 degrees internal temperature?

A I do.

Q And did you sell some of that fish?

A No.

Q Did you deliver some of it to a customer named Flamf?

A Yes.

Q You delivered some to Mr. Flamf; is that correct?

A That's correct.

Q What happened to it?

A Mr. Flamf made sure to call us and ask to pick it up and return the invoice. And on the invoice he wrote something to the effect that this --

Q Did he write, "Returned. Cannot sell this junk"?

A That's correct. You ought to know that. I gave --

MR.MC MORROW: Your Honor, I object to this. We don't have Mr. Flamf here. We don't have --

MR. EINSTEIN: It's evidence to show the receipt of complaints that the fish prepared in this manner --

THE WITNESS: I have other things. I have a letter from a customer who, when he read the devastating publicity in the newspaper, which was very much uncalled for --

(continued next page)

MR. MC MORROW: I object to this line of questioning, your Honor. It has no bearing.

THE WITNESS: Customers are complaining -- Your Honor, I received a letter from a long-time customer who -- and the letter is on the table over there -- who said he couldn't believe what he read in the newspapers, that Food & Drug was using us as not having enough salt in our product, or the reason he has refused his business with us was because our fish has been saltier than others that he is able to buy in the same market.

Q Mr. Sklar, are you generally familiar with the processing parameters of the other smoked fish manufacturers in and around the New York City area?

A Yes, I am.

Q Do you know whether any of them on a regular and consistent basis processes their hot smoked whitefish at an internal temperature of 180 degrees --

MR. MC MORROW: I object to this on relevancy grounds, again, your Honor.

THE COURT: This is on his last point on the effect of his firm being enjoined when others have not. And he is --

MR. MC MORROW: I point out, your Honor, that's not an adequate defense for the allegations that the

regulations have been violated.

THE COURT: No, that's quite right. It goes to the question of whether or not the relief sought for the violation should be granted on a balancing of equities viewpoint, which may be quite irrelevant.

MR. EINSTEIN: Would you read the question back, please.

THE COURT: Is anyone in the area, insofar as he knows, in compliance?

THE WITNESS: I will agree with Miss Kolaitis, who testified in the inspection she made that she found the other companies were not in compliance and I concur.

Q Both as to temperature and salt?

A Both as to temperature and salt.

MR. EINSTEIN: You may inquire.

THE COURT: A short recess.

MR. MC MORROW: Thank you.

(A recess was taken.)

CROSS-EXAMINATION

BY MR. MC MORROW:

Q Now, Mr. Sklar, you stated that you were -- you commented on the proposed GMP's and you had meetings with the Food & Drug Administration and representatives -- industry

representatives. Isn't that correct?

A Yes.

Q And you said they couldn't be complied with, certain of the GMP's?

A Certain aspects of the GMP's, yes.

Q When did you first start investigating the possibility of using an electronic oven or ovens other than the gravity ovens which you have in your plant?

A Approximately 1972 I started investigating.

Q And you purchased the oven when?

A In 1974.

Q When did you commence experimental production with the oven?

A In 1975.

Q So you were aware that technologies were available which might limit you to process fish, to cook the fish in a manner which might enable you to meet the GMP's?

A That has not been determined as yet, Mr. Mc Morrow. I have not determined it and there are other sophisticated ovens in our industry that are not able to do it.

Q But the GMP's went into effect in 1970 and yet you waited -- it was not until 1974 that you actually purchased an oven yourself to attempt to produce fish in compliance with the GMP's?

A The GMP to me was never a lawful requirement. It was a guideline and an advisory -- in my opinion, at all times in particular in view of FDA's conduct with me each year.

Q When you say the FDA's conduct, you mean the inspection of the inspector?

A No. I mean the meetings with compliance officers and officials of Food & Drug in our district who discussed with me the fact that they were not meeting the temperature and brining requirements.

Q So regardless of how you characterized the GMP's, though, you were not adhering to them at the time, to certain portions of them?

A Yes.

Q And the inspectors who conducted the annual -- however often it may be -- the inspection of your plant, told you you were not complying with certain of the provisions in the GMP's. Isn't that correct?

A Yes, that's correct.

Q Why do you think they pointed out the fact that you were not in compliance with certain provisions of the GMP's?

MR. EINSTEIN: Objection.

THE COURT: Overruled.

A Well, they were instructed to observe and see if we were. And if we weren't, they told us. That's the reason they told us.

Q Mr. Sklar, what percentage of your business was actually whitefish? What percentage does a whitefish account for?

A I would say maybe eight to ten percent.

THE COURT: Eight to what?

THE WITNESS: Eight to ten, eight up to ten percent.

Q Of your total business?

A Yes.

Q Apart from purchasing the electronic oven in 1974, have you made any attempts to acquire more sophisticated or other technologies that might enable you to produce the fish in accordance with the GMP's?

A Such as what, Mr. Mc Morrow?

Q I don't know. I am asking what efforts you have made.

Let me ask you, have you consulted with any food technology experts?

A I am always in contact with food technology experts. We have -- my company subscribes to or is a member of the Association of Smoked Fish Processors. We are constantly

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discussing new techniques, available techniques. We have operated our plant. We have added chill rooms which we consider extremely important to maintain the safety of the product. I think that's one of the most important things. And we have -- all our equipment is sanitary approved and specially made.

We have operated our processes. We are constantly alert to the importance of maintaining a safe product. And we are gratified to see that in the 13 years since 1963 --

Q Mr. Sklar, I think your reaching a little afield.

A I wouldn't interrupt you, Mr. Mc Morrow. You asked me a question and I am telling you since 1963 there hasn't been one incident of botulism in commercially produced smoked fish.

Q That wasn't my question, Mr. Sklar.

A I intended it -- You asked me if we upgraded our technical ability to comply and make a safe product and I am saying the best evidence is no injury of any kind whatsoever.

Q That's not responsive to my question.

Has your firm consulted -- not through the Association or not through the NFI, have you consulted experts on food technology with respect to acquiring equipment which would enable you to produce fish in compliance with the GMP's?

A Can you be more specific, Mr. Mc Morrow?

Q Have you or your firm consulted with a person or company other than the Association of which you are a member, with respect to receiving technical advice regarding equipment which you might be able to use to produce fish in compliance with the GMP's?

A What equipment is necessary?

Q I am asking you, Mr. Sklar.

A I think it's a fishing kind of expedition, kind of question.

Q I don't know. I am not a smoked fish processor. I am asking you.

A I don't know either. Do you want to know if I have consulted with technological people on sophisticated type ovens? The answer is yes. If I consulted with refrigeration experts on keeping temperatures, the answer is yes.

What else is there? If I consulted with people on temperature recorders, the answer is yes. Have I done anything about recording thermometers on my ovens, even though the inspector was there and didn't find them, the answer as I have already testified, the answer is yes; answer is yes.

THE COURT: But the answer I get from you is, no, that you have not consulted anybody on the question, who is apparently qualified on the question of how to

achieve compliance with the GMP regulation.

THE WITNESS: Your Honor --

THE COURT: And produce a marketable product.

THE WITNESS: Your Honor --

THE COURT: What you said is that you have dealt with people who can do particular things, build an oven, build a refrigerator and build a recording thermometer and advise you of its use.

Now, the question is: Have you consulted anyone the way you would consult a management consultant, so a fish, baked smoked fish or other prepared fish consultant who can deal with the whole area of the flow sheets through the plant, the kind of equipment to use, the regimen of plant operation which would best assure compliance with the GMP's, et cetera, et cetera?

Are there any such creatures in the first place?

THE WITNESS: Well, that's a good question, your Honor. There is someone, and I have consulted with him and I have had him on a retainer basis as a technical consultant. And they have written up a legend on the proper handling of fish. And this someone, other than Dr. George Beerman from the Association of Smoked Fish Processors, and other than Mr. Roy Martin, Technical Director of the National Fisherman's Institute --

with this consultant we were attempting to adopt our conventional ovens to perform that which we felt was necessary.

We finally decided it would be necessary to buy one of these sophisticated ovens.

So, therefore, the answer to your question is yes.

Q You stated that you consulted with these people to do what you thought was necessary. Did you --

A No.

Q Did you --

A What the GMP calls for, that's what we did.

Q So you have experimented using steam injection in your brick ovens or using other forms of humidity control?

A Yes.

Q Could you describe those forms of humidity control that you have experimented with?

A Yes. I testified to that on my examination before.

Our brick ovens is so situated, as Miss Kolaitis so described to you, where there are gas jets on the lower and the bottom part of either side of the oven. Covering these gas jets is a flat plate similar to a cover on a gas range that we may have at home. But it's a very long piece of metal

and it covers the gas jets.

We attempted to boil water on these. And it was very easy to boil the water because the temperature gets very, very hot in one of our gravity ovens.

I found, for example, since you want to have some knowledge as to this, it is easier to get a higher ambient temperature in our old gravity ovens than it is in our sophisticated ovens. So we did that.

And we also installed in one of these gravity ovens a dry bulb and a wet bulb so we can determine what the relative humidity would be in that oven.

We did that, oh, many years ago, about 1971 or '72. It was at the end of '72 that I felt that this was not going to work under a controlled process and, therefore, I went to Europe and looked into a sophisticated electronic oven. I ultimately didn't buy that particular make, but I did get one in Europe of another make. And as I formerly told you, having installed it in 1974.

We were constantly on the lookout for methods in which to comply with the GMP insofar as it was humanly possible.

Q Do you attach a special importance in your processing procedures to the relative humidity of the oven? Does that make a difference in the product?

A It makes a very big difference, Mr. Mc Morrow.

Q Is the humidity in your gravity ovens relatively low?

A The humidity in the gravity ovens fluctuates according to the weather.

Q Is there any way for you to control that humidity?

A No. I have tried and experimented.

Q Have you experimented with injecting steam directly into the ovens?

A We did it in the manner I have described it.

Q Well, other than creating steam within the oven?

A No.

Q So you haven't used an independent steam source?

A It would be --

THE COURT: Steam injection?

THE WITNESS: Steam injection.

Since the oven is not closed and not a controlled environment, it would be equally ineffective.

Q But you haven't experimented with that?

A No.

Q Mr. Sklar, you stated that you attempted to reach a salt level of approximately 2.75 percent in the water phase, didn't you?

A No, I didn't state that at all. I said it was

the effect. We tried to retain 3-1/3 percent salt because the good manufacturing processes call for it. But by the very nature of the fish, the nature of rinsing it, washing it, et cetera, we -- I testified that we retained an average of 2.77, something like that.

THE COURT: Is this a convenient place to stop for lunch, gentlemen?

MR. MC MORROW: Yes, your Honor.

MR. EINSTEIN: Yes.

THE COURT: We will resume at five after two.

(Whereupon, a luncheon recess was taken.)

FL:CR
LPM all

A F T E R N O O N S E S S I O N
(Time noted 2:15 P.M.)

THE COURT: Sorry to be late, but I had to take a telephone call which refused to end.

I'm sure you have all had the experience.

Go ahead, Mr. McMorrow.

CROSS EXAMINATION

BY MR. MC MORROW(Continued):

Q Mr. Sklar, I have only a few more questions.

First with respect to the electronic oven with which you are now experimenting, is it true that the temperature of that oven can exceed 180 degrees?

A The ambient temperature?

Q Yes.

A Yes.

Q Can the temperature in that oven be controlled?

A Yes.

Q Can it be controlled with more accuracy than the temperature in the brick ovens?

A Yes.

Q Are you able to control the relative humidity within the electronic oven?

A Yes.

Q Have you had any problems in experimenting in controlling the relative humidity in the electronic oven?

A No real problem.

Q Are you able to accurately guage or record what the relative humidity is within the electronic oven?

A Yes.

Q Now, how many smokers do you employ, and smoker's assistants?

A Smoker's assistants?

Q Well, assuming that there is such a --

A Yes, we haveone smoker for full-time and one smoker assistant. And a part-time smoker.

Q Have your smokers and assistants and part-time smokers been trained in the operation of the electronic oven?

A They are being trained, yes.

Q You say they are being trained now?

A Yes.

Q Were they trained in the operation of the oven at the time that you conducted experiements with it?

A They were part of the experiments.

Q So part of the experiment was in training your personnel as well as producing the fish?

A That's correct.

Q Have you consulted with the manufacturer of theelectronic oven concerning utilizing it to process fish in accordance with the GMP's?

A Very much so.

Q Has the manufacturer or manufacturer's representative consulted with you in your factory regarding the operation of the oven?

A Yes.

Q And he's actually assisted you in operating the oven?

A That's correct.

Q Have you sought technical assistance from any engineers or food technologists who are expert in the area of thermal control or heat transfer within food with respect to using the oven to process the fish in accordance with the GMP's?

A Not other than those mentioned already.

Q So you haven't consulted any expert as such other than the manufacturer of the oven itself.

MR. EINSTEIN: Excuse me, your Honor, that's not an accurate summary of his testimony.

He said before the lunch break that he had consulted another technical expert on this oven.

Q But did you consult that other technical expert with respect to the functioning of this particular electronic oven?

A No.

Q You testified earlier that the new oven has

the capability of doing something different than the brick ovens that you have utilized in the past, that you were presently experimenting and that your experiments were not yet completed.

Is it not possible or feasiable that the electronic oven may be utilized to produce a product which is processed in compliance with the GMP's?

A I'm hoping that it will be, but so far we haven't been able to manifest that it is.

Q But you have not as of yet consulted with expert engineers or food technologists who are expert in the area of heat transfer within foods to assist you in operating this particular oven to produce fish in complianze with the GMP's; is that correct?

A I consider the manufacturer or the manufacturer's representative as having enough experience to be experts in that field.

Q Well, is this an ove which is manufactured especially for or primarily for smoking fish?

A No, it's an oven that is manufactured for smoking meats, but it has been adapted to fish.

Q So the expertise of the manufacturer would be primarily in the area of processing meats?

MR. EINSTEIN: Objection. I don't know how

he would be able to speculate on that, your HMnor.

THE COURT: Well -

MR. MC MORROW: I withdraw the question.

Q Now, with respect to your brining procedures, do you periodically add salt to the brining tank during the brining process?

A Generally we don't do that but of late we have been adding salt to the top layer of the fish in brine.

Q What effect does that have?

A It has the effect of taking care of the fish that are sort of swimmin on the top. A concentrated salt brine keeps the product floating a little bit, and --

THE COURT: In other words, that just takes the place of want of total immersion.

THE WITNESS: Yes, sir, your Honor.

Q Is the absorption of salt by fish uniform within the entire period of time that the fish are in the brining solution; in other words, do they absorb the same amount of salt throughout the brining process or do they absorb more salt at the beginning?

A They absorb more salt at the beginning and less towards the end of the brining process.

Q Have you experimented with adding salt during the brining process for the purpose of improving the

consistency of salt uptake by the fish which are in the brining solution?

A No, I haven't done that but I have double-brined fish.

Q But you have not experiemented with adding the salt?

A No.

Q Do you use any sort of centrifugal pump or similar device to periodically agitate the brine?

A No.

Q Do you agitate the brine?

A Manually we do.

Q How often?

A Several times during the brining procedure.

THE COURT: How many?

THE WITNESS: Several times.

Q Have you explored the possibility of installing a pump or mechanical device which would agitate the brine at regular intervals?

A We have thought about it, but we haven't really explored it actively.

Q Incidentally, how do you measure the intensity of the brine or --

THE COURT: The saturation.

Q The saturation, the salt content.

A There is a thing called a salometer. It's kind of a thermometer which floats in the brine and will show on an indicater on this thermometer --

THE COURT: Like a hygrometer?

THE WITNESS: Exactly, sir.

Q And what does that indicate?

A It indicates the strength or weakness of the brine.

And it indicates the percentage of salt in the brine in relation to the water.

(Continued on the next page.)

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PM-2

THE COURT: You mean the higher it floats the more salt there is in the brine?

THE WITNESS: That's correct, the higher it floats. And there is -- there are gradations on the tool. It's a tool with a certain -- with a sort of a lead -- quantity of lead on the bottom so that it sits up straight in a cylinder.

You fill up the cylinder with the brine, drop this hydrometer in and you just read the strength of the brine.

Q What are the readings, how are they indicated?

A They go from 100 saturated brine down to as low as ten, or even zero.

THE COURT: That's a percentage scale in terms of total saturation at what temperature?

THE WITNESS: Generally at I think it's somewhere around '65 degrees, at that temperature. It varies very slightly --

THE COURT: Toward room temperature?

THE WITNESS: Yes, sir.

Q That device indicates the percentage of salt in the water?

A You mean percentage by weight or the strength -- it indicates --

THE COURT: Degree of saturation, as I understand it, is that it?

THE WITNESS: Sir?

THE COURT: Degree of saturation.

THE WITNESS: The degree of saturation, exactly.

Q It's the degree of solubility of the water, of salt?

A Degree of saturation.

THE COURT: In other words, if it was at the 100% mark to add salt would just precipitate salt?

THE WITNESS: Excactly, your Honor.

THE COURT: It's only when you get below the 100 that you could add salt without precipitating salt?

THE WITNESS: That's correct.

THE COURT: That's all the high school chemistry I can remember.

THE WITNESS: That's all I know also.

Q I was just trying to clarify the point that it measures not the percentage of salt which is in the water, but the solubility of the water itself, or the saturation.

Now, you stated in your testimony that you

intend to expand your factory, processing factory and in connection therewith you hoped that you would be able to meet the GMP's; is that correct?

A Yes.

Q And that the -- that would cost you approximately $500,000.

A Yes.

Q Would you please tell us how long do you think it will be before this plant is in operation?

A Well, it's been almost a year ahalf now that we have been working on it and we have just about gotten everything down pat.

We have even contacted Food and Drug Administration and asked them to go over our plans. They have agreed to do so.

In the interim, however, this summons and complaint came through, and I don't know whether we 're going to be delayed materially because of this particular action in court now, because those bankers who have promised us to lend us the money for mortgage purposes have withdrawn temporarily pending the developments in this particular case, because if we're going to be cited in any way they feel, as I already stated, that even if we would just refrain from producing white fish it would effect our business.

the rest of our business so materially that they would not want to make any further investment.

Q Well, assuming that you can get the financing, Mr. Sklar, how long do you anticipate it will be before your plant would be in operation?

A It would be in operation, if we receive the proper financing, in less than a year. I would say maybe nine months, because everything is ready to go.

We have already invested in this over $20,000 in architects' fees, engineers' fees, surveyors, pile drivers, everything in connection with getting ready to take off.

Q But your financing was not certain even prior to this --

A That's correct.

Q -- proceeding; is that right?

A The budget was completed, I received a call only the other day that the financing is pretty much set, but we have a problem now because of these proceedings.

Q But in any event, it would not be less than nine months or a year from now.

Q Even if you were to get the financing?

A I don't think that it would be less than nine months, but I think nine months is a very short period of time.

Q Well, until that time do you plan to install any other electronic ovens in your present processing facility?

A It's not in our plans because before we install any additional ovens we have to have the necessary support, such as the additional refrigerators, work rooms, storage rooms for fish on the cages, et cetera. But it is part of our plan as soon -- soon after the extension is erected and as soon as practicable to replace all our gravity ovens with the sophisticated ones similar to the one we havenow.

Q But at this point it remains a plan; is that correct?

A It's more than a plan, sir.

Q With respect to your purchase of white fish you stated earlier that your white fish come from Canada; is that correct?

A Yes.

Q Whereabouts in Canada do they come from?

THE COURT: What?

Q They come from Canada; is that not correct?

A Not every pound of white fish that we get comes from Canada. But I would say like approximately 97% of it does. And the 97% of it is purchased from a Canadian Government, a Crown company called Fresh Water

Marketing Board.

THE COURT: Which?

THE WITNESS: Fresh Water Fish Marketing Board. It's a semi-Governmental agency which controls the sale of white fish out of Canada, the white fish that we smoke.

Q Do you know exactly what lakes or what bodies of water in Canada --

A Yes.

Q -- the fish come from?

A Every carton is marked according to the source. There are two basic lakes. One is Lake Winnipeg and the other is the Great Slave Lake.

Q Do you occasionally hit white fish from other bodies of water in Canada?

A Sometimes.

Q Do you ever purchase white fish from the Great Lakes area?

A We used to.

Q Do you ever have occasion to purchase itnow?

A It depends. It depends on the availability. We have used some Lake Huron whitefish.

Q So you occasional purchase whitefish from the Great Lakes?

A Yes.

Q Now you have described this process of I believe it's washing the fish with the chlorinated water; is that a correct term?

A Yes.

Q Do you rinse the fish in this water or do you dip them?

A The manner in which it's done is that the vat is rolled over to a chlorine solution outlet.

We open the faucet and at the end of the faucet there is a hose. The hose is placed in the vat and the water is allowed to move and agitate the fish and overflow.

Q Does this take place before or after the clearning operation?

A Before the cleaning.

Q So is there another expression for the cleaning process?

A Well, we call it scaling or cleaning.

Q Do you remove any viscera that may have been left, is that --

A It there is any viscera left we remove it as well as the scales on the outside of the fish.

Q The chlorinated water does not in any way

get inside the fish then, it washes over the fish; is that correct?

A Well, it will go through the fish as much as anything else would go through fish.

Q But the cleaning operation takes place subsequent to that?

A That's our procedure at this time. We find that if a different procedure would be desirable we will change as we always do to try to update and upgrade.

(Continued on the next page.)

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MR. MC MORROW: I have no further questions.

REDIRECT EXAMINATION BY

MR. EINSTEIN:

Q Mr. Sklar, 99 per cent of your fish do come from those two lakes in Canada?

A Yes.

Q And the $500,000 that you mentioned for plant expansion, was that including electronic ovens?

A No.

Q Those would be additional expenses over and above this five hundred thousand?

A That's correct.

Q I see. Now, you mentioned this morning that you had consulted with a food technician. Just for the record, what is the name of the man or his company?

A The company's name is called Bacto-Free. The individual's name is Martin Mithcell.

Q Now, your also testified that white fish represents eight to ten per cent of your total business. Is it a particularly profitable or unprofitable area of your business?

A Yes, it's profitable in and of itself, and also because it brings other business along with it. The absence of which, if we were prevented from handling white fish, it

would seriously interfere with the plans of our business, and the damage would be considerably greater than the ten per cent.

MR. EINSTEIN: Nothing further.

RECROSS EXAMINATION BY

MR. MC MORROW:

Q Am I to understand, Mr. Sklar, with the electronic -- you presently propose -- Strike the question.

You presently propose to install electronic ovens in the new facility which you are building?

A Eventually, yes.

Q But you do not propose, then, to install electronic ovens at the time -- Or you don't propose that the electronic ovens will be part of the facility which could possibly be completed within nine months to a year?

A It is not possible for me financially to be able to swing both the things at the same time. And in choosing one over the other, it's the logical choice. It has to go first, the support facility, and then the ovens themselves. To fill those ovens, we have to have the extension.

Q Now, you stated that white fish is eight to ten per cent of your business, but it takes on an importance and it may be in excess of that percentage?

A Yes, sir.

Q Has this always been the case?

A Yes.

Q Was it the case in '63?

A Yes.

Q 1968-1969 when the regulations were promulgated?

A Yes.

Q If this is such an important and profitable part of your business, why did you not prior to this time, or prior to the time of the purchase of the electronic ovens take steps to experiment with current technologies or with technologies which might be available to assist you in trying to produce a product in compliance with the GNP?

MR. EINSTEIN: I think this is an argumentative question, your Honor.

THE COURT: Well, I think it's essentially an argument, and I believe I appreciate it.

MR. MC MORROW: I have no further questions.

THE COURT: You may step down.

THE WITNESS: Thank you, sir.

(Witness excused.)

MR. EINSTEIN: Your Honor, we are going to need a few moments of your indulgence to bring in some fish and to get it set up.

I am also, your Honor, contrary to our stipulation with Mr. Mc Morrow --

THE COURT: Are you going to have a table setting?

MR. EINSTEIN: We will put it on counsel table.

We are going -- We have three witnesses in the court room and we are going to exclude them while each of them is testifying because we want the individual views of each. So I'm going to ask Mr. Gilman, Mr. Sabar, and Mr. Cutler to step out of the court room at this time and we will call you as you are needed.

And at this time I want to call Dr. Behrman back for the purpose of identifying the fish and the method in which it was prepared.

MR. MC MORROW: Your Honor, I would like to indicate for the record that we, of course, strenuously object to this method of operation to the presentation of this -- of this fish. I don't want —

THE COURT: Let me first get one thing straight. You were not invited to the test?

MR. MC MORROW: Absolutely not, your Honor. We didn't know about it until today.

THE COURT: So that we will be bound on what Dr. Bierman is able to tell us about how it was conducted.

MR. MC MORROW: I want to make it clear that we object to this whole line of testimony and the production of these specimens. We think that this is

totally irrelevant, again, as we have indicated before, and that it's far beyond the scope of what should be this Court's review in this action.

THE COURT: Yes. But I suppose we all should be here and should have a proper attitude toward things And I'd be surprised and delighted if the fish turned out to be absolutely perfect and tasty.

MR. EINSTEIN: I will represent to your Honor that the three gentlemen who are going to taste this fish have never seen --

THE COURT: What?

MR. EINSTEIN: That the three gentlemen who are going tc pass opinions on this fish have never seen or sampled it before.

I think Dr. Bierman was previously sworn.

THE COURT: Have they got their papers, their certificates?

MR. EINSTEIN: I think we will be able to qualify all three of them.

D O C T O R B I E R M A N , having been previously duly sworn, took the stand and testified as follows:

REDIRECT EXAMINATION BY

MR. EINSTEIN:

Q Doctor Bierman, during the week of May 10, 1976 did you personally cook and smoke some fish at the Vita and

Nova Scotia plants in New York City?

A Yes, sir, I did.

Q All right. How many batches of fish did you smoke at the Vita plant?

A Three.

Q All right. Now, will you tell us in what manner you smoked or cooked each of the three batches at the Vita plant?

A The three batches consisted of what are considered to be their regular production. There was one cooked in accordance with the GNP at 150 degrees for 30 minutes.

Q What salt content?

A The salt content in the fish of that batch was about 5.3.

THE COURT: That's 150 degrees, 30 minutes, 5.3?

THE WITNESS: Right. I might mention that during the test we probed four fish. And this was based on the coldest fish that we probed. We probed one of the largest fish and it represented the coldest fish, the loin muscle temperature.

Q What was the second batch that you cooked at Vita?

A Well, the first batch was the regular product.

The second batch was 150, and the third batch was 180.

Q You say it was a regular product? What do you mean by that?

A This was prepared in accordance with their normal brining procedures and smoked with their normal cooking operation.

Q Do you know what the temperature and salt content of that is, the regular batch?

A The temperature varied between 146, I believe, and 156 at 30 minutes.

Q What was the salt content of that which you call the regular batch?

A About 3.7 per cent.

Q All right. Now, did you also cook some fish at Nova Scotia?

A I did, yes.

Q All right. Will you tell us what you did there?

A Excuse me. I also cooked a third batch at Vita.

Q I am sorry. I thought we had all three.

A No. We did a regular, which was approximately 3.1 per cent salt. It was cooked for an oven temperature of -- in the fish, the cold smoking fish, to 146 to 156, which was the variation, I believe, for thirty minutes, in the loin muscle. The 150 temperature for 30 minutes. And those fish

contained about 5.3 per cent salt.

Q All right. Now, what did the .3 patch that you cooked at Nova Scotia --

A Excuse me. The third one, that batch was 180 degrees.

THE COURT: This was at Vita?

THE WITNESS: Vita.

Q What was the salt content?

A The salt content in that product was about 3.7 per cent.

Q Now, you also cooked three batches at Nova Scotia; is that correct?

A Yes, sir, we did.

Q All right. What was the cooking parameter of salt on those three batches?

A These three batches were cooked in the gravity oven, regular batch. A one process in accordance with the GNP procedure of 150 degrees for 30 minutes. And the third one was 180 degrees for 30 minutes.

Q All right. Now, the regular batch --

A I think I should mention, this is the end of the cook and the temperature at the time at 180.

Q In the regular batch, what was the temperature and salt content?

A The temperature -- I would have to refresh my memory on that one. I am not quite sure.

Q Do you have some records that you want to look at?

A Yes.

MR. EINSTEIN: May he step down, your Honor, and get some records?

THE WITNESS: Well, the temperature varied back and forth during the cooking operation. But based on this chart, I would say that 150 degrees Farenheit for over thirty minutes on this one.

Q What was the salt content on that regular batch?

A It was about 4.4.

Q 4.4 per cent.

And what was the salt content on the 150 degree batch?

A The salt content was 100 -- I'm sorry, it was 4.6.

Q 4.6.

You were shooting for 5 per cent on that, but you fell a little short?

A Yes.

Q All right. What was the salt content on the 180?

A That was 4 - 3.

Q 4.3 per cent?

A Yes.

Q Now, at Vita, what kind of ovens did you use?

A Vita has Alkar electronic ovens. They are controlled in air velocity, temperature, humidity, and smoking.

Q Did you engage in this cooking process at Vita with employees of Vita?

A Yes, I did.

Q Did you follow the regular and routine processes that Vita normally follows in cooking their fish in these electronic ovens?

A Yes. In the one we did by their regular procedure.

Q Did that include humidity control?

A No.

Q What kind of -- What did you do with respect to the humidity?

A Pardon me?

Q What did you do with respect to the humidity?

A We did not control it. It was based on the natural humdity of the atmosphere.

Q Can you identify among these boxes, so that we can tag them, which ones are the Vita and which fall into each of the classifications?

A Yes. The Vita boxes are marked Vita. And I believe each box is appropriately marked. And each of the fish within the box is marked based on the probe that we have recorded here on the charts.

Q Well, Doctor Bierman, I will ask you if you can -- to label each box. I will ask you to put an A next to the regular Vita batch; B next to the 180 batch; a C next to the 150 batch; and then a D next to the Nova Scotia regular; and then an E next to the Nova Scotia 180; and an F next to the Nova Scotia 150, just so we can identify these.

Doctor Bierman, on A, on the Vita regular --

A B for boy on 180.

Q B for boy on the Vita 180, C for Charlie on the 150, D on the regular Nova Scotia; E on the 180 Nova Scotia.

A E on the 180.

Q Yes, sir. And F on the 150 Nova Scotia.

MR. EINSTEIN: You may enquire.

CROSS EXAMINATION BY

MR. MC MORROW:

Q Doctor Bierman, did you actually physically particpate in the cooking and smoke these fish?

A Yes, sir, I did.

Q Did you run the machine or the ovens?

A I was right there with the operator when he was setting up the charts.

Q Did you personally know the operators of the ovens?

A Yes.

Q Did you know what their qualifications were?

A Yes.

Q Now, with respect to the ovens at the Vita plant, you referred to it as an Alkar?

A Alkar Rasputin.

Q What distinction did that oven have from the cnventional gravity oven?

A It's not a brick oven. It's a stainless steel lined oven. the ovens -- They are fairly large. They are probably ten feet across, perhaps twenty feet deep, and perhaps ten feet high. The ovens have a stainless steel forum. The heat is controlled externally to the oven or in a chamber avove the normal plane of the oven. The air is forced air. There is a spout along the topside of the oven. They have the capability of injecting steam for humidity control. The smoke is generated externally to the oven and their operator is completely closed.

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Q Now, during the three cooking and smoking operations at Vita which you have -- the results of which you brought into court, was the steam injection feature of the ovens used?

A It was used on only one batch.

Q Which batch was that?

A The 180° batch.

Q Do you know what the controls of the machine were set at?

A When the temperature setting -- the dry bulbwas set at 140, and we started to control the humidity with the wet bulb temperature. So the wet bulb temperature attained a relative humidity of 40 per cent.

Q Does that mean that there was an indicator on the oven which told you that the -- the level of relative humidity was forty per cent?

A There is a chart that designates the dry bulb temperature and the wet bulb temperature in the oven. And it's a calculation of what the -- the humidity is based on those two temperatures.

Q In other words, you calculated the humidity yourself?

A That's correct.

Q Based on --

A The temperature from a chart.

Q Is there a dial or control of any device on the oven which you can use to actually set the humidity?

A Yes.

Q And what was that set at?

A It went up -- actually, we set it to attain the proper humidity. It's got a 100 division scale. And it was set to attain the proper humidity on the recorder. The proper wet bulb temperature of the humidity. We h8d predetermined what the -- based on incremental increases in the dry bulb temperature, and what wet bulb temperature we needed to attain 40 per cent relative humidity. So as we increased the dry bulb temperature we correspondingly adjusted the wet bulb control to attain the wet bulb temperature on the chart that we were looking for.

Q Now, do you have any assurance that the temperature -- the humidity within the oven was actually at 40 per cent?

A No more than what the instrument told us.

Q Now, you referred to this regular product, this -- this Vita regular product. Do you know what a Vita regular product is?

A I have seen their regular products, yes.

Q Have you taken time temperature recordings or

monitorings of their regular products?

A Many years ago I did, yes.

Q But you haven't in recent years?

A Not other than this and working with the people that were actually the -- the quality assurance people and the monitoring people in the plant. And that assured me that it was the regular product.

Q So the only assurance you have of the regular product is what they told you?

A That's correct. And they operated the oven in the normal procedure. I didn't tell them how to operate the oven.

Q Do you know that that was the normal procedure?

A I have looked at other charts that they have operated and it's typical of the other charts that I saw in previous operations for whitefish.

Q So you are basing your conclusions on the -- that this was their normal procedure on the basis of the charts which you have reviewed in the past?

A That's correct.

Q Did you do the salt analysis?

A Their laboratory did the salt analysis.

Q Doesn't your laboratory normally do the salt analysis?

A We do salt analysis. At this time Vita cooperated with us and did the salt analysis as we were proceeding.

Q So the only assurance that we have that the salt is as represented, 3.1 per cent with respect to the regular product is the representation of an analyst that Vita employed for that purpose?

A Right. And the -- who does this regular thing.

Q Would the salt content be the same in all the samples?

A I would say no.

Q Do you know how much is going to vary?

A I don't know. But I know that --

THE COURT: Do you mean within the regular product?

MR. MC MORROW: Within the products that are here now.

THE COURT: No. I mean within the regular -- 150 or 180.

MR. MC MORROW: Within each of them. Within the fish which comprise each --

THE WITNESS: The salt will normally vary within the fish in any one batch. I mean there are a number of factors that control the salt level. As I think

Mr. Sklar indicated, it's a natural product and there are variation among fish of the same batch.

Q Now, with respect to all six batches which we have here now, do you have personal knowledge of the method in which they were brined?

A No, I do not.

Q Just to clarify one point: Is every fish which is part of the samples before us now probed during the cooking?

A Yes. And I have the temperature record of each of those fish.

Q With respect to the salt concentration of all of the Vita batches, the three subject batches which were cooked at Vita that you are relying upon for all three batches, both the 180 and the 150, and the regular, you are referring upon the analysis that there --

A By their analytical chemist.

Q What about the batch at Nova Scotia?

A The batch at Nova Scotia, my technician did that.

Q Youdidn't personally do them?

A I did not do them. But I was accompanied by a chemist from my laboratory who did them.

Q Now, based on 4.4 per cent, 4.6 per cent, and 4.3 per cent, do you in your ordinary course of business do salt analysis for Nova Scotia?

A Yes, we do.

Q Is that higher than the customary salt content?

A I would say generally these were a little higher than we normally get, yes, sir.

Q Again, the assertion or your assertion that these are average, are they -- excuse me --

These are average salt temperatures or sale content?

A Yes. These are salt content from fish from the same batch that the processed fish were from.

Q They were from the same batch?

A Yes. They are not the same fish. We destroyed the fish to do the salt content.

Q To do the testing to determine the salt content, you have destroyed the fish?

A Yes.

Q So the fish which are here now obviously are not the same fish which were used to determine the average -- what you claim is the average salt content of the specimens before us.

A That's correct. They are not the exact fish. But the ones we did the analysis from, it is the same procedure, the same brining and handled identically in the same manner.

Q But you stated that the -- that generally the salt content varies from fish to fish?

A That's correct.

Q And you are not personally familiar with the brining procedures that were used by either plant in preparing the specimens?

A I am acquainted with it. I did not attend the brining operation. But I am familiar with what was done.

Q But you didn't see it or monitor it?

A No.

MR. EINSTEIN: Your Honor, if there is the least bit doubt about the salt content in this fish, we would be happy to have the FDA take them back tonight and test it and then tell us what their technicians say. They have the facilities here in New York.

THE COURT: I am sure if you renew the offer later on you will get a reaction to it.

MR. MC MORROW: I have no further questions, your Honor.

REDIRECT EXAMINATION

BY MR. EPSTEIN:

Q Just one question, Doctor: In each of these six batches, there are four fish in each batch?

A Yes.

THE COURT: In each what?

MR. EINSTEIN: In each batch there are four fish. There are six boxes. Each one contains four fish. We have a total of twenty-four fish.

Will you ask Mr. Gilman to step in, please?

You may step down, Dr. Bierman.

(Witness excused.)

MR. MC MORROW: I would like to preserve for the record the objection which I have made --

THE COURT: Yes.

MR. MC MORROW: (Continuing) -- throughout the proceeding and I want to assert that same objection with respect to the testimony of Dr. Bierman this time around.

THE COURT: Very well.

MR. EINSTEIN: Mr. Gilman, will you take the stand, please, at least temporarily?

STATE OF NEW YORK)
COUNTY OF NEW YORK) ss.:

ALLEN Q HAYES, being duly sworn, deposes and says that deponent is not a party to the action, is over 18 years of age and resides at 162 NAVY Walk Brooklyn N.Y. 11201 Apt 6D.

That on the 20 day of DEC, 1976, deponent personally served the within JOINT APPENDIX VOLUME I OF II upon the attorneys designated below who represent the indicated parties in this action and at the addresses below stated which are those that have been designated by said attorneys for that purpose.

By leaving 2 true copies of same with a duly authorized person at their designated office.

~~By depositing _____ true copies of same enclosed in a postpaid properly addressed wrapper, in the post office or official depository under the exclusive care and custody of the United Stated post office department within the State of New York.~~

Names of attorneys served, together with the names of the clients represented and the attorneys' designated addresses.

DAVID G. TRAGER
UNITED STATES ATTORNEY FOR THE
EASTERN DISTRICT OF NEW YORK
ATTORNEY FOR PLAINTIFF-APPELLEE
225 CADMAN PLAZA EAST
BROOKLYN, N.Y. 11201

Allen Q Hayes

Sworn to before me this
20 day of December, 1976

Michael DeSantis

MICHAEL DeSANTIS
Notary Public, State of New York
No. 03-0930908
Qualified in Bronx County
Commission Expires March 30, 1978